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PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

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Memorandum

Subject: PP#s 7F04910, 8F04997 - **Human Health Risk Assessment for the Food Use of Glufosinate Ammonium on Potatoes, Transgenic Sugar Beets and Transgenic Canola.** DP Barcodes: D257590, D258417. Submission #s: S545114, S529287. Case #s: 289177, 290273. Chemical #: 128850. EPA Registration Numbers: 45639-187 (Rely®) and 45639-199 (Liberty™).

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AgrEvo requests the establishment of a permanent registration for use of glufosinate ammonium on potatoes, transgenic sugar beets and transgenic canola. A summary of the human health risk resulting from the requested and registered uses of glufosinate ammonium is provided in this document. The hazard assessment was provided by Myron S. Ottley, Ph.D. of Registration Action Branch I (RAB1), the residue chemistry and dietary exposure assessment was provided by Tom Bloem of RAB1, the occupational and residential risk assessment was provided by Myrta Christian of RAB1, and the water exposure assessment was provided by Laurence Libelo of the Environmental Fate and Effects Division (EFED).

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1.0 EXECUTIVE SUMMARY

The petitioner is requesting registration of Liberty™ Herbicide (18.19% glufosinate ammonium; EPA Reg. No. 45639-199) for use on the transgenic varieties of sugar beet and canola and Rely® Herbicide (11.33% glufosinate ammonium; EPA Reg. No. 45639-187) for use in potato vine dessication. Concentrations of active ingredient in the formulated products are reported in terms of the racemic mixture (D and L isomers). Only the L isomer is herbicidally active.

Glufosinate ammonium is a non-selective, postemergent herbicide which acts as an inhibitor of glutamine synthetase, a critical enzyme in ammonium fixation and detoxification in plant cells. Formulated products of glufosinate ammonium are water soluble concentrates which are applied as a foliar spray. Current registrations include broadcast application to apple, grape, banana and tree nut orchards (time-limited tolerances ranging from 0.05 - 0.3 ppm) and to the transgenic varieties of field corn and soybeans (time-limited tolerances ranging from 0.2 - 25.0 ppm). Tolerances are also established as a result of secondary residues in milk, eggs, and the meat, fat and meat byproducts of ruminants and poultry (time-limited tolerances ranging from 0.05 ppm - 0.10 ppm). Prior to this petition, tolerances were established on a time-limited basis due to a lack of a rat carcinogenicity study. A Section 18 request from Wisconsin for use on transgenic sweet corn has been approved (4.0 ppm tolerance).

Hazard Profile

Glufosinate ammonium (racemic mixture of glufosinate ammonium; D and L isomer) is in toxicity category III for acute oral, dermal and inhalation toxicities and for eye irritation. It is not a dermal irritant or sensitizer. For subchronic toxicity, the primary effects of concern in the mouse were increased liver and kidney weights with increases in serum aspartate amino transferase and alkaline phosphatase. Signs of neurotoxicity, such as aggressive behavior, piloerection, high startle response, and increased incidence of fearfulness, were observed in subchronic rat studies.

Chronic studies in the rat demonstrated increased mortality, increased occurrence of retinal atrophy, inhibition of brain glutamine synthetase, and increased liver and kidney weights. In the mouse, increase mortality and changes in glucose levels consistent with changes in glutathione levels were observed. Increased mortality and EKG alterations were observed in dogs. There was no evidence of a treatment-related increase in tumors in rats and mice.

The developmental toxicity study in the rat resulted in dilated renal pelvis and/or hydroureter in the offspring at levels that resulted in significant increases in hyperactivity and vaginal bleeding in dams. In the rabbit, decreased fetal body weight and increased fetal mortality were observed; while in rabbit does, decreased food consumption, body weight and body weight gain were observed. The reproductive toxicity study indicated systemic and postnatal developmental toxicity in the form of increased kidney weights in parents and a decrease in viable pups in all generations.

Based on the lack of mutagenic potential as assessed in a battery of mutagenic assays, and the absence of treatment-related tumors in rats and mice at dose levels adequate for assessment, glufosinate ammonium has been classified as a "not likely" human carcinogen.

A dermal absorption study with rats indicated that about 50% of the given radioactivity was absorbed 48 hours after a single dose application. In other metabolism studies, it was shown that over 80% of administered radioactivity is excreted within 24 to 48 hours as the parent compound in the feces and urine. Highest tissue levels were found in liver, kidney and gonads.

Additional testing was conducted using 3-methylphosphinico propionic acid, N-acetyl glufosinate and the L-isomer of glufosinate ammonium (major metabolites found in plants and animals). These compounds, tested in subchronic rat, mouse and dog studies, and in developmental toxicity studies in rat and rabbit, showed a similar toxicity profile as the racemic mixture of glufosinate ammonium (D- and L-isomers). Since formulated products of glufosinate ammonium are a racemic mixture of the D and L isomers, HOE 039866 (DL-glufosinate ammonium) is the compound that is deemed appropriate for endpoint selection.

FQPA Safety Factor

There are no guideline data gaps for assessment of glufosinate ammonium following *in utero* and/or postnatal exposure. The data provided no indication of increased susceptibility in rats or rabbits to pre or postnatal exposure to glufosinate ammonium. A consistent pattern of neurotoxicity was seen in several studies, including the subchronic, developmental, and chronic studies in rats, mice and dogs. In addition to the clinical signs, such as hyperactivity, aggressive behavior, piloerection, and high startle response, retinal atrophy was observed. Changes in glutamine synthetase levels were observed in liver, kidney and brain in rats. Based on the toxicity profile, HED is requesting acute, subchronic and developmental neurotoxicity studies in rats. **Although there were no signs of increased susceptibility, the FQPA Safety Factor Committee determined that a safety factor of 3 should be retained because of data gaps for the assessment of neurotoxicity. The FQPA safety factor is applicable to all population subgroups and risk assessments (acute/chronic dietary and residential).**

Toxicological Endpoints

Acute Dietary: An acute RfD was not established for the general population. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicity studies. However, an acute RfD of 0.063 mg/kg/day was established for the females 13 - 50 subgroup, based on a developmental NOAEL of 6.3 mg/kg/day in the rabbit and a 100x uncertainty factor (10x inter- 10x intra-species extrapolation). The developmental LOAEL (20 mg/kg/day) was based on reduced fetal body weight and increased fetal death. Using a 3x FQPA safety factor, the acute population adjusted dose (aPAD) for glufosinate ammonium is 0.021 mg/kg/day.

Chronic Dietary (non-cancer): The chronic RfD of 0.021 mg/kg/day was established, based on the NOAEL of 2.1 mg/kg/day in the 2-year chronic study in rats and a 100x uncertainty factor (10x inter- 10x intra-species extrapolation). The LOAEL in this study was based on increased kidney weight and kidney/brain weight in males at 52 weeks (6.8 mg/kg/day) and decreased survival in females at 130 weeks (8.2 mg/kg/day). Using a 3x FQPA safety factor, the cPAD for glufosinate ammonium is 0.007 mg/kg/day.

Short-, Intermediate- and Long-Term Dermal: The FQPA safety factor of 3 is applicable to residential risk assessments only (acceptable MOE of 300 for residential and 100 for occupational risk assessments).

Short- and intermediate-term dermal risk assessments were recommended based on neurological clinical signs (hyperactivity, aggressive behavior, piloerection) observed in the 21-day dermal study in rats at 300 mg/kg/day (LOAEL). The NOAEL was 100 mg/kg/day.

Long-term dermal risk assessment was recommended based on the NOAEL of 2.1 mg/kg/day established in the 2-year chronic study in rats (see chronic dietary; 50% dermal absorption).

Short- and Intermediate-Term Inhalation: With the exception of an acute inhalation study, no inhalation studies are available. Therefore, oral NOAELs were selected for inhalation risk assessments. Since an oral dose is used, the exposure assessments will be conducted by converting the application rate to oral equivalents and assuming 100% absorption. The FQPA safety factor of 3 is applicable to residential risk assessments only (acceptable MOE of 300 for residential and 100 for occupational risk assessments).

Short-term inhalation risk assessments were recommended based on the developmental NOAEL of 6.3 mg/kg/day in the rabbit (see acute dietary endpoint).

Intermediate-term inhalation risk assessments were recommended based on the NOAEL of 2.1 mg/kg/day from the 2-yr chronic rat study (see chronic dietary endpoint).

Drinking Water Exposure Assessment

Glufosinate ammonium is water soluble and stable to hydrolysis and photolysis. The soil and aquatic anaerobic half-lives of glufosinate ammonium are such that sustained concentration in surface water is not likely. Due to the high water solubility of glufosinate ammonium, it will reach ground water relatively quickly and thereby counteract the degradation seen in surface water. The Environmental Fate and Effects Division (EFED) estimates acute and chronic ground water concentrations at 1.16 ppb (SCI-GROW) and acute and chronic surface water concentrations at 34.1 ppb and 0.79 ppb, respectively (PRZM/EXAMS; Tier 2).

Occupational/Residential Risk Estimates

Occupational: The proposed use on potatoes and the transgenic varieties of canola and sugar beets will result in short- and intermediate-term exposures to mixer/loaders and applicators. Post-application occupational exposure is not anticipated to be a concern based on the use pattern and the fact that planting and harvesting of the subject crops are mechanized. The potential short- and intermediate-term exposures to workers (commercial and private) do not exceed HED's level of concern (estimated MOEs > 350).

Residential: Glufosinate ammonium is registered for residential use as a spot treatment around trees, shrubs, fences, walks, patios, driveways, sidewalks, and flower beds. It is also registered for lawn renovation uses. Only short-term residential exposures are expected from the registered uses of glufosinate ammonium. The contribution from inhalation exposures to the overall risk was not significant. **The handler and post-application dermal exposure estimates from the existing residential uses are above HED's level of concern (handler MOE of 217 [garden use]; post-application MOEs of 100 for adults and 110 for children [lawn renovation use]).** Due to the lack of chemical specific data, the dermal exposure estimates were based on high-end scenarios and assumptions for regular lawn uses (from the Draft HED SOPs for residential exposure assessment), which are not necessarily applicable to lawn renovation uses. These assumptions represent a Tier 1 assessment and therefore are expected to overestimate the real potential risk.

Aggregate Risk Estimates

Acute Aggregate Risk: The acute dietary exposure analysis for females 13 - 50 (no acute dietary endpoint was identified for the general US population including infants and children) assumed tolerance level residues and 100% crop treated for all registered and proposed commodities (Tier 1 analysis). The most highly exposed population among females 13 - 50 was nursing females at 58% of the aPAD (95th percentile). The estimated glufosinate ammonium concentrations in surface (34.1 ppb) and ground water (1.16 ppb) are less than HED's drinking water level of comparison (DWLOC; 270 ppb for females 13 - 50 nursing). Acute aggregate exposure to glufosinate ammonium, as a result of all registered and proposed uses, is below HED's level of concern.

Chronic Aggregate Risk: Since there are no chronic residential exposure scenarios, the chronic aggregate risk assessment is concerned with food and water only. The chronic dietary exposure analysis assumed tolerance level residues for all registered and proposed commodities and incorporated the weighted average percent crop treated for all registered commodities (sweet corn maintained at 100% crop treated; Tier 2 analysis). For the most highly exposed subgroup (children, 1-6 years), 71% of the cPAD is occupied by dietary (food) exposure. The estimated glufosinate ammonium concentrations in surface (0.79 ppb) and ground water (1.16 ppb) are less than HED's DWLOC (20 ppb for children 1-6 years). Chronic aggregate exposure to glufosinate ammonium, as a result of all registered and proposed uses, is below HED's level of concern.

Aggregate Short- and Intermediate-Term Risk: Short- and intermediate-term aggregate risk assessments include average dietary exposure (food and water) and short- or intermediate-term dermal and inhalation exposures from residential uses. The dermal exposure estimates from the registered residential uses of glufosinate ammonium are above HED's level of concern (inhalation exposures were insignificant). According to HED policy (HED SOP 97.2), the residential dermal exposures cannot be aggregated with chronic dietary exposure because different endpoints were chosen for these exposure scenarios.

Recommendations for Tolerances

The potential risks (from dermal exposures) for the registered residential lawn renovation use are above HED's level of concern. However, these risks result from toxic effects that are different from the ones attributed to dietary exposure. Therefore, the estimated risks from the residential uses cannot be aggregated to the potential dietary risk. The HED Risk Assessment Review Committee concluded the following (RARC Report, 24-Aug-1999):

> This risk assessment is unique in that the dermal and dietary endpoints are completely different. A reasonable argument could be made for this particular food use safety finding: Dietary risk plus all other risks with the same toxic effect do not result in an aggregate risk concern; since this petition deals only with dietary risks and water (both using oral endpoints), there is no unacceptable risk considering the only toxicity endpoint associated with this petition. Toxicity expected from the dermal exposure route does not contribute to the risk considering only the oral endpoints which are the only ones associated with the proposed uses. The RARC recommended that RD and OGC be consulted to determine the best course.

The following deficiencies were identified in the toxicological and residue chemistry databases:

- Acute Neurotoxicity, Subchronic Neurotoxicity and Developmental Neurotoxicity Studies (Guidelines 81-8, 82-7 and 83-3; respectively)
- A Revised Section B (Liberty™ and Rely®)
- Storage stability Study for Sugar Beet Processed Commodities (sugar, pulp and molasses; 3 months; Guideline 860.1380)
- Successful Petition Method Validation for Methods BK/04/95 (sugar beets) and HRAV-24 (canola)

Pending resolution of the deficiencies listed above and the residential exposure issues, HED concludes that the toxicological, residue chemistry and occupational exposure databases support the establishment of the following tolerances, for the combined residues of glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid, expressed as glufosinate free acid equivalents.

Beet, Sugar, tops (Leaves)	1.5 ppm
Beet, Sugar, root	0.9 ppm
Beet, Sugar, molasses	5.0 ppm
Canola, seed	0.4 ppm
Canola, meal	1.1 ppm
*Potato	0.8 ppm
*Potato, chips	1.6 ppm
*Potato, granules/flakes	2.0 ppm

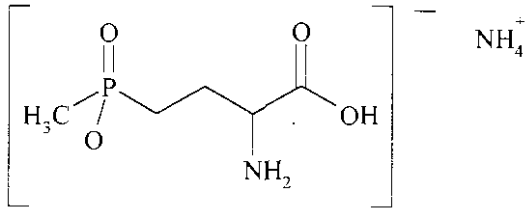
* Tolerance expression for commodities derived from potatoes are for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents (non-transgenic crop).

Since glufosinate ammonium has been classified as a "not likely" human carcinogen, the previously established time-limited tolerances can be made permanent.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

Glufosinate-ammonium (herbicide) is a racemic mixture of the D and L isomers; only the L-isomer is herbicidally active. Concentrations in the technical and formulated products are reported in terms of the racemic mixture. Impurities present in the technical grade product and in the end use product are not presently considered to be of toxicological concern.

Chemical Name:	ammonium-DL-homoalanin-4-yl (methyl phosphinate)
Common Name:	glufosinate ammonium
PC Code Number:	128850
CAS Registry No.:	77182-82-2
Empirical Formula:	$C_5H_{15}N_2O_4P$
Molecular Weight:	198.19
Vapor Pressure:	not determinable
Partition Coefficient (n-Octanol/Water):	<0.1
Water Solubility:	1370 mg/l



3.0 HAZARD CHARACTERIZATION

The HIARC (Memo, M.S. Ottley, 17-May-1999) and FQPA Safety Factor Committee (Memo, B. Tarplee, 17-May-1999) reports are included as Attachments 1 and 2, respectively.

3.1 Hazard Profile (Tables 1 and 2)

Glufosinate ammonium (also referred to as DL-glufosinate ammonium or HOE 039866) is toxicity category III for acute oral, dermal, and inhalation toxicities, and for eye irritation. It is not a dermal irritant or sensitizer. For subchronic toxicity, the primary effects in the mouse were increased liver and kidney weights with increases in serum aspartate amino transferase and alkaline phosphatase. Signs of neurotoxicity were observed in rats in subchronic studies, such as aggressive behavior, piloerection, high startle response, and increased incidence of fearfulness.

In the chronic rat studies, increased mortality, increased occurrence of retinal atrophy, and inhibition of brain glutamine synthetase were observed, as were increased liver and kidney weights. In the mouse, increased mortality was observed, as were changes in glucose levels consistent with changes in

glutathione levels. Increased mortality and EKG alterations were observed in dogs. **There was no evidence of a treatment-related increase in tumors in rats and mice.**

The developmental toxicity study in the rat resulted in dilated renal pelvis and/or hydroureter in the offspring at levels that resulted in significant increases in hyperactivity and vaginal bleeding in dams. In the rabbit, decreased fetal body weight and increased fetal mortality were observed at 20 mg/kg/day; while in rabbit does, decreased food consumption, body weight, and body weight gain were observed at 6.3 mg/kg/day.

The reproductive toxicity study indicated systemic and postnatal developmental toxicity at 6.0 mg/kg/day in the form of increased kidney weights in parents, and a decrease in viable pups in all generations. Since parental and developmental effects were observed at the same dose levels, **there is no evidence of increased susceptibility in offspring.**

A **consistent pattern of neurotoxicity was seen** in several studies, including the subchronic, developmental and chronic studies in rats, mice and dogs. In addition to the clinical signs, such as hyperactivity, aggressive behavior, piloerection, and high startle response, retinal atrophy was observed. Changes in glutamine synthetase levels were observed in liver, kidney and brain in rats. Based on the toxicity profile, HED is requesting acute, subchronic and developmental neurotoxicity studies in rats (HIARC Report, 17-May-1999). It is expected that these studies will provide the information needed to further characterize the neurotoxic effects.

There is no concern for mutagenic activity as indicated in the following studies: Salmonella E. Coli, *in vitro* mammalian cell gene mutation assays, mammalian cell chromosome aberration assays, *in vivo* mouse bone marrow micronucleus assays, and unscheduled DNA synthesis assays.

A dermal absorption study in rats indicated that about 50% of the given radioactivity was absorbed 48 hours after a single dose application. In other metabolism studies, it was shown that over 80% of administered radioactivity is excreted within 24 to 48 hours as the parent compound in the feces and urine. Highest tissue levels were found in liver, kidney and gonads.

Additional testing was conducted with the following major metabolites: HOE 061517 (3-methylphosphinico propionic acid, HOE 099730 (N-acetyl glufosinate), as well as HOE 058192 (L-isomer of the parent). These compounds, tested in subchronic rat, mouse and dog studies, and in developmental toxicity studies in rat and rabbit, showed a similar profile of toxicity as the parent compound (HOE 039866). Since formulated products of glufosinate ammonium are a racemic mixture of the D and L isomers, HOE 039866 (DL-glufosinate ammonium) is the compound that is deemed appropriate for endpoint selection.

Data Gaps: Three data gaps have been identified at this time: acute neurotoxicity, subchronic neurotoxicity and developmental neurotoxicity. These studies are requested because of concern for the neurotoxic effects observed in several studies and in multiple species. It is also requested that glutamine synthetase levels be measured in the subchronic neurotoxicity study to assist the Agency in characterizing these effects.

Table 1: Acute Toxicity of Glufosinate Ammonium Technical

Study Type	Results	Toxicity Category
81-1 acute oral–rat MRID 41796102	LD_{50} 4010 mg/kg in males LD_{50} 3030 mg/kg in females	III
81-2 acute dermal MRID 41796103	LD_{50} > 2000 mg/kg in males & females	III
81-3 acute inhalation MRID 41846302	LC_{50} 4.42 mg/L estimated in males & females	III
81-4 eye irritation MRID 072962	eye irritant; corneal opacity reversible within 7 days	III
81-5 dermal irritation MRID 41796105	not a dermal irritant	IV
81-6 sensitization MRID 41796106	not a dermal sensitizer	NA

Table 2: Subchronic and Chronic Toxicity Profile of Glufosinate Ammonium [1]

[1]Study Type	MRID	NOAEL (mg/kg/day)	LOAEL (mg/kg/day)	Based On
2-YR FEED/CARCINOGENIC RAT (HOE 039866) (1986)	40345607	2.1 mg/kg/day	6.8 / 8.2 mg/kg/day (M/F) No evidence of ↑ tumors	↑ kidney & brain wt in males. ↑ mortality in females NO TUMORS Inhibition (11%) brain GS Females at 28.7 mg/kg
18-MN CARCINOGENIC MOUSE (HOE 039866) (1986)	41144702	10.82 / 16.19 mg/kg/day (M/F)	22.60 / 63.96 mg/kg/day (M/F) No evidence of ↑ tumors	↑mortality & glucose levels. consistent changes in glutathione levels. etc.
2-YR CARCINOGENICITY RAT (HOE 039866) (1989)	44539501	45.4 / 57.1 mg/kg/day (M/F)	228.9 / 281.5 mg/kg/day (M/F) No evidence of ↑ tumors	⇑ levels of retinal atrophy.
1-YR CHRONIC FEEDING DOG (HOE 039866) (1989)	40345608	5.0 mg/kg/day	8.5 mg/kg/day	⇑ mortality alterations in EKG
2-GEN. REPRO. RAT (HOE 039866) (1988)	40345612	systemic: 2 mg/kg/day repro/develop: 6 mg/kg/day	systemic 6 mg/kg/day repro/develop: 18 mg/kg/day	↑kidney wts M + F decr viable pups in all generations
DEVELOP. TOXICITY RAT (HOE 039866) (1986)	40345610	maternal: 10 mg/kg/day develop: 250 mg/kg/d	maternal: 50 mg/kg/day develop.: 250 mg/kg/day	vaginal bleeding and hyperactivity dilated renal pelvis and/or hydroureter
DEVELOP. TOXICITY RABBIT (HOE 039866) (1984)	4114703	maternal: 2.0 mg/kg/day develop: 6.3 mg/kg/day results shown in table 3 of DER. NOT CLEAR-CUT	maternal: 6.3 mg/kg/day develop: 20 mg/kg/day	↓food consumption ↓ BW & BW gain. ↑ kidney wt absent/incomplete ossification ↓ body weights fetal death
13-WEEK FEEDING MOUSE (HOE 039866) (1986)	40345609	48 mg/kg/day (M) 192 mg/kg/day (F)	192 mg/kg/day (M) >192 mg/kg/day (F)	↑ rel & abs kidney & liver weights. ↑ (30% M) serum aspartate amino transferase ⇑ (38% females) serum alkaline phosphatase
21-DAY DERMAL RAT (HOE 039866) (1985)	40345605	100 mg/kg/day	300 mg/kg/day	aggressive behavior. piloerection. high startle response
METABOLISM RAT (HOE 039866) 1993	43766913			Excreted in 24 hr. mostly as parent cpd. 80% M 73% F

[1]Study Type	MRID	NOAEL (mg/kg/day)	LOAEL (mg/kg/day)	Based On
METABOLISM RAT (HOE 039866) (1995)	43766914 43778402			excr in 24- 48 hr. as parent cpd 80% M 88% F little sequestered in tissues.
METABOLISM Single Oral Dose in Rat (HOE 039866) (1985)	40345640			excreted as parent 88/84% in M/F, resp. highest levels in liver kidney gonads
METABOLISM Repeated Oral Dose in Rat (HOE 039866) (1985)	40345642			major route is feces. Increased radioactivity in tissue compared with single dose study.
13-WK FEEDING MOUSE (HOE 061517 metabolite) (1989)	44076207	1121 / 1340 mg/kg/day (M/F)	not established	not applicable
13-WK FEEDING RAT (HOE 061517 metabolite) (1989)	44076206	102 mg/kg/day	420 mg/kg/day	Males only: marginal liver wt incr. & ↑ incid. of small Kupffer cell proliferates and ↑ reticulocyte counts.
13-WEEK FEEDING DOG (HOE 099730 metabolite) (1994)	44076201	147 / 162 mg/kg/day (M/F)	738 / 800 mg/kg/day (M/F)	inhibition of brain glutamine synthetase
14-WK ORAL FEEDING RAT (HOE 058192 isomer) (1989)	44068501	18.5 / 19.8 mg/kg/day (M/F)	91.8 / 100.3 mg/kg/day (M/F)	↑ NH_3 levels in plasma & urine, slight ↑ kidney wt
13-WEEK FEEDING DOG (HOE 099730 metabolite) (1989)	44076203	19 / 21 mg/kg/day (M/F)	72 / 79 mg/kg/day (M/F)	inhibition of brain glutamine synthetase
13-WEEK FEEDING DOG (HOE 058192 isomer) (1989)	44068502	2 mg/kg/day	5 mg/kg/day	↑ NH_3 levels in plasma & kidney.
DEVELOP. TOXICITY RAT (HOE 099730 metabolite) (1992)	44076204	Maternal: 1000 mg/kg/day Develop: 1000 mg/kg/day	Maternal: > 1000 mg/kg/day Develop: > 1000 mg/kg/day	not applicable
DEVELOP. TOXICITY RAT (HOE 061517 metabolite) (1994)	44076209	maternal: 300 mg/kg/day develop: 300 mg/kg/day	maternal: 900 mg/kg/day develop.: 900 mg/kg/day	one death, persistent piloerection and/or ↑ urinary output, ⇑abs kidney wt. ⇑ incidence of total litter loss ↑ incidence (fetal & litter) of wavy and/or thickened ribs.

[1]Study Type	MRID	NOAEL (mg/kg/day)	LOAEL (mg/kg/day)	Based On
DEVELOP. TOXICITY RABBIT (HOE 058192 isomer) (1992)	43829405	maternal: 1.25 mg/kg/day develop: 1.25 mg/kg/day	maternal: 2.5 mg/kg/day develop: 2.5 mg/kg/day	↓bw & bw gain & food consumption; neurotoxic signs (severe spasms, lateral recumbency, muscle twitching), abortions ↑ fetal resorptions
DEVELOP. TOXICITY RABBIT (HOE 099730 metabolite) (1995)	44076205	maternal: 64 mg/kg/day develop: 64 mg/kg/day	maternal: 160 mg/kg/day develop: 160 mg/kg/day	reduced food consumption uni or bilateral extra rib at the 13th thoracic vertebra
DEVELOP. TOXICITY RABBIT (HOE 061517 metabolite) (1994)	44076210	maternal: 50 mg/kg/day develop: 200 mg/kg/day	maternal: 100 mg/kg/day develop: >200 mg/kg/day	↓ food & water consumption, fecal output; ↑abortions and mortality no develop effects.
PHARMACOKINETICS WITH DERMAL APPLICATION (HOE 039866) (1986)	40345620			42.5 to 50% absorbed at 0.1 mg 26% absorbed at 10 mg Mostly excreted via urine Minimal amounts in brain relative to liver and kidney
13-WK FEEDING MOUSE (HOE 99730 metabolite) (1994)	44076202	<83 mg/kg/day (M) 110 mg/kg/day (F)	83 mg/kg/day (M) 436 mg/kg/day (F)	inhibition of brain glutamine synthetase
MUTAGENICITY: DNA Damage & Repair (HOE 039866) (1984) Gene Mutation (HOE 039866) (1984)	072962 072962	not mutageuic not mutagenic		no DNA damage no reverse mutation
MUTAGENICITY: Unscheduled DNA Synthesis (HOE 039866) (1984)	40345614	not mutagenic		no evidence of inhibition of DNA synthesis
MUTAGENICITY: Mouse Lymphoma Forward Mutation (HOE 039866) (1988)	40345616	not mutagenic		did not increase mutation frequency
MUTAGENICITY: Mouse micronucleus assay (HOE 039866) (1986)	41144704	non-mutagenic		no effect on micronucleus formation

[1] HOE 039866 = glufosinate ammonium. HOE 058192 = L-isomer of glufosinate ammonium. HOE 061517 = 3-methylphosphinico propionic acid. HOE 099730 = N-acetyl glufosinate

3.2 FQPA Considerations

There are no guideline data gaps for assessment of glufosinate ammonium following *in utero* and/or postnatal exposure. The data provide no indication, either quantitatively or qualitatively, of increased susceptibility in rats or rabbits, to pre- and/or post-natal exposure to glufosinate ammonium. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproductive study in rats, any observed toxicity to the fetuses or offspring occurred at equivalent or higher doses as the toxicity to parental animals. A consistent pattern of neurotoxicity was seen in several studies, including the subchronic, developmental and chronic studies in rats, mice and dogs. In addition to the clinical signs such as hyperactivity, aggressive behavior, piloerection, and high startle response, retinal atrophy was observed. Changes in glutamine synthetase levels were observed in liver, kidney and brain in rats. Based on the toxicity profile, acute, subchronic and developmental neurotoxicity studies in rats were requested (HIARC Report, 17-May-1999). **Although there were no signs of increased susceptibility, the FQPA Safety Factor Committee determined that a safety factor of 3 should be retained because of data gaps for the assessment of neurotoxicity. The FQPA safety factor is applicable to all population subgroups and risk assessments (acute/chronic dietary and residential).**

3.3 Dose Response Assessment

Acute Dietary: An acute RfD was not established for the general population. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicity studies. However, an acute RfD of 0.063 mg/kg/day was established for the females 13 - 50 subgroup, based on a developmental NOAEL of 6.3 mg/kg/day in the rabbit and a 100x uncertainty factor (10x inter- 10x intra-species extrapolation). The developmental LOAEL (20 mg/kg/day) was based on reduced fetal body weight and increased fetal death. Using a 3x FQPA safety factor, the aPAD for glufosinate ammonium is 0.021 mg/kg/day.

Chronic Dietary (non-cancer): The chronic RfD of 0.021 mg/kg/day was established, based on the NOAEL of 2.1 mg/kg/day in the 2-year chronic study in rats and a 100x uncertainty factor (10x inter- 10x intra-species extrapolation). The LOAEL in this study was based on increased kidney weight and kidney/brain weight in males at 52 weeks (6.8 mg/kg/day) and decreased survival in females at 130 weeks (8.2 mg/kg/day). Using a 3x FQPA safety factor, the cPAD for glufosinate ammonium is 0.007 mg/kg/day.

Chronic Dietary (cancer): Glufosinate ammonium has been classified as a **"not likely"** human carcinogen according to the EPA *Proposed Guidelines for Carcinogen Risk Assessment*. The HED HIARC assigned this classification to glufosinate ammonium (HED Doc. No 013385) based on the lack of mutagenic potential as assessed in a battery of mutagenicity assays, and the absence of treatment-related tumors in rats and mice at dose levels adequate for assessment.

Short-, Intermediate- and Long-Term Dermal: The FQPA safety factor of 3 is applicable to residential risk assessments only (MOE of 300 for residential and 100 for occupational risk assessments).

Short- and intermediate-term dermal risk assessments were recommended based on neurological clinical signs (hyperactivity, aggressive behavior, piloerection) observed in the 21-day dermal study in rats at 300 mg/kg/day (LOAEL). The NOAEL was 100 mg/kg/day.

Long-term dermal risk assessment was recommended using the oral NOAEL of 2.1 mg/kg/day established in the 2-year chronic study in rats (see chronic dietary; 50% dermal absorption).

Short- and Intermediate-Term Inhalation: With the exception of an acute inhalation study, no inhalation studies are available. Therefore, oral NOAELs were selected for inhalation risk assessments. Since an oral dose is used, the exposure assessments will be conducted by converting the application rate to oral equivalents and assuming 100% absorption. The FQPA safety factor of 3 is applicable to residential risk assessments only (MOE of 300 for residential and 100 for occupational risk assessments).

Short-term inhalation risk assessments were recommended using the developmental NOAEL of 6.3 mg/kg/day in the rabbit (see acute dietary endpoint).

Intermediate-term inhalation risk assessments were recommended using the oral NOAEL of 2.1 mg/kg/day from the 2-yr chronic rat study (see chronic dietary endpoint).

Table 3: Endpoint Selection Summary

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	developmental NOAEL = 6.3 [1]UF = 300	LOAEL = 20 mg/kg/day based on decreased fetal body weight and increased fetal death	developmental toxicity–rabbit
		Acute RfD = 0.063 mg/kg/day (females 13 - 50only) **aPAD** = 0.021 mg/kg/day no acute RfD for the general population including infants and children was identified	
Chronic Dietary	NOAEL = 2.1 [1]UF = 300	LOAEL = 6.8 / 8.2 mg/kg/day in males / females based on increased kidney weight and kidney/brain weight in males at 52 weeks, and decreased survival in females at 130 weeks.	Two-year chronic toxicity/carcinogenicity in rat
		Chronic RfD = 0.021 mg/kg/day **cPAD** = 0.007 mg/kg/day	
Short-Term (Dermal)	NOAEL = 100 [2]MOE = 300	LOAEL = 300 mg/kg/day based on clinical observations (aggressive behavior, piloerection & high startle response)	21-day dermal–rat
Intermediate-Term (Dermal)	NOAEL = 100 [2]MOE = 300	LOAEL = 300 mg/kg/day based on clinical observations (aggressive behavior, piloerection & high startle response)	21-day dermal–rat
Long-Term (Dermal)	NOAEL = 2.1 [2]MOE = 300	LOAEL = 6.8 / 8.2 mg/kg/day **oral** in males / females based on increased kidney weight and kidney/brain weight in males at 52 weeks, and decreased survival in females at 130 weeks. **50% dermal absorption demonstrated.**	Two-year chronic oral toxicity/carcinogenicity in rat
Short-Term (Inhalation)	developmental NOAEL = 6.3 [2]MOE = 300	LOAEL = 20 mg/kg/day based on decreased fetal body weight and increased fetal death	developmental toxicity–rabbit

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Intermediate-Term (Inhalation)	NOAEL = 2.1 [2]MOE = 300	LOAEL = 6.8 / 8.2 mg/kg/day **oral** in males / females based on increased kidney weight and kidney/brain weight in males at 52 weeks, and decreased survival in females at 130 weeks.	Two-year chronic oral toxicity/carcinogenicity in rat
Long-Term (Inhalation)	NOAEL = 2.1 [2]MOE = 300	LOAEL = 6.8 / 8.2 mg/kg/day **oral** in males / females based on increased kidney weight and kidney/brain weight in males at 52 weeks, and decreased survival in females at 130 weeks.	Two-year chronic oral toxicity/carcinogenicity in rat

[1] UF = uncertainty factor; 100 for intra/inter species extrapolation and 3 for FQPA safety factor
[2] acceptable MOEs: 300 for residential risk assessments and 100 for occupational risk assessments (FQPA safety factor not applied to occupational risk assessments)

4.0. EXPOSURE ASSESSMENT

A complete review of information pertaining to residue chemistry can be found in Attachment 3 (D257629 & D257628, T. Bloem, 9-July-1999).

4.1 Summary of Registered/Requested Uses

Glufosinate ammonium is a non-selective, postemergent herbicide which acts as an inhibitor of glutamine synthetase, a critical enzyme in ammonium fixation and detoxification in plant cells. Formulated products of glufosinate ammonium are water soluble and applied as a foliar spray. Current registrations include use on both transgenic and non-transgenic crops. Transgenic plants contain a gene (phosphiothrion-acetyl-transferase) which enables the plant to metabolize the herbicidally active moiety of glufosinate-ammonium into a N-acetyl glufosinate (2-acetamido-4-methylphosphinico-butanoic acid; not herbicidally active). This metabolite is found only in transgenic plants. The tolerance expression for non-transgenic crops and animal commodities includes glufosinate ammonium and 3-methylphosphinico propionic acid. The tolerance expression for transgenic crops includes these two compounds along with the N-acetyl glufosinate metabolite.

Current registrations include broadcast application to apple, grape, banana and tree nut orchards (4.5 lbs ai/acre/year; pre-harvest interval (PHI) = 14 days; time-limited tolerances ranging from 0.05 - 0.3 ppm) and to the transgenic varieties of field corn and soybeans (0.73 lb ai/acre/season; PHI = 60 days for corn forage and 70 days for corn grain, corn fodder, and soybean seed; time-limited tolerances ranging from 0.2 - 25.0 ppm). Tolerances are also established as a result of secondary residues in milk, eggs, and the meat, fat and meat byproducts of ruminants and poultry (time-limited tolerances ranging from 0.05 ppm - 0.10 ppm). Prior to this petition, tolerances were established on a time-limited basis due to a lack of a rat carcinogenicity study. A Section 18 request from Wisconsin for use on transgenic sweet corn has been approved (0.64 lb ai/acre/season; PHI = 70 days; 4.0 ppm tolerance). Residential registrations include use in lawn renovation and spot treatment.

The petitioner is requesting registration of Liberty™ Herbicide (18.19% glufosinate ammonium; 1.67 lbs ai/US gallon; EPA Reg. No. 45639-199) for use on the transgenic varieties of sugar beet and canola and Rely® Herbicide (11.33% glufosinate ammonium; 1.00 lb ai/US gallon; EPA Reg. No. 45639-187) for use in potato vine dessication.

Sugar Beets: Applications of Liberty™ Herbicide may be made from the cotyledon stage up to the 10-leaf stage. The maximum recommended single application rate is 0.55 lb glufosinate ammonium/acre. A maximum of 1.1 lbs ai/acre can be applied per season. Applications can be made with ground or aerial equipment. The label specifies a 60-day pre-harvest interval (PHI).

Canola: Applications of Liberty™ Herbicide may be made from the cotyledon stage up to the early bolting stage (at this stage the plant has at least 6 leaves). A maximum of two applications per season is allowed with the total seasonal rate not to exceed 0.89 lb ai/acre. Applications can be made with ground or aerial equipment. The label specifies a 65-day PHI. The petitioner requested a higher use rate (1.56 lbs ai/acre/season) for canola grown for seed (seed retained for planting in the future).

Potato: Application of Rely® Herbicide is recommended at the beginning of natural vine senescence. The product is to be applied at a rate of 0.38 lb ai/acre with ground or aerial equipment. The label specifies a 9-day PHI. Potatoes grown for seed stock are not to be treated.

The Chemistry Science Advisory Committee determined that canola grown for seed is a food use and therefore requires a tolerance (Chem SAC Minutes, 21-Jul-1999). To establish a tolerance, the petitioner must submit field trial data reflective of the requested use rate (1.56 lbs ai/acre). Currently, HED has canola field trial data which demonstrates residue levels resulting form application of glufosinate ammonium at 0.71 - 0.98 lb ai/acre. Therefore, the information pertaining to the higher use rate for canola grown for seed should be eliminated from the Liberty™ label. The "Restrictions to the Directions for Use" section of the Liberty™ label for sugar beet and canola indicates application rates in ounces/acre. Application rates should be in fluid ounces/acre. The petitioner should submit a revised Section B.

4.2 Dietary Exposure

4.2.1 Food Exposure

Nature of the Residue - Plants and Animals (OPPTS GLN 860.1300)

Plants: The nature of the residue is considered to be understood in genetically unaltered lettuce, soybeans, corn, apples and wheat. After application of ^{14}C glufosinate ammonium to the nutrient medium (water or soil) in which these crops were grown, only one labeled metabolite could be identified, 3-methylphosphinico propionic acid. The residues of concern in/on commodities derived from genetically unaltered lettuce, soybeans, corn, apples and wheat are glufosinate ammonium and 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990).

The nature of the residue is considered to be understood in transgenic field corn and transgenic soybeans. After application of ^{14}C glufosinate ammonium to these crops, the major residues identified were glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid. The residues of concern in/on commodities derived from the transgenic varieties of field corn and soybean are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate (D211531 and D219069, M. Rodriguez, 7-Mar-1996).

In support of the requested registration, the petitioner submitted metabolism studies performed on transgenic sugar beets and transgenic canola.

Transgenic Sugar Beets: The nature of the residue in transgenic sugar beets is considered to be understood. Transgenic sugar beets were treated twice with C^{14} glufosinate ammonium at 1.0x the proposed maximum single rate (total applied was 1.0x the proposed maximum seasonal). Samples collected 0 and 21 days following the second application, and at maturity (146 days following the second application) were divided into tops and roots and analyzed. For all samples, glufosinate ammonium, N-acetyl glufosinate and 3-Methylphosphinico-propionic acid accounted for 93-98% of the total radioactive residue (TRR).

The current tolerance expression for commodities derived from transgenic crops includes the major residues identified in the transgenic sugar beet metabolism study and is therefore adequate. The residues of concern in/on commodities derived from transgenic sugar beets are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate.

Transgenic Canola: The nature of the residue in transgenic canola is considered to be understood. Transgenic canola was treated once with C^{14} glufosinate ammonium at 0.8x the proposed maximum seasonal rate. Samples were collected 1-hour post treatment (whole plant), 21-day post-treatment (separated into top growth and roots) and at maturity (120 days after treatment; separated into roots, top growth and seed).

In the whole plant harvested 1-hour post-treatment, glufosinate ammonium and N-acetyl glufosinate accounted for 91% of the TRR. In foliage harvested 21 days post-treatment, 88% of the TRR was identified as N-acetyl-glufosinate, glufosinate ammonium and 3-methylphosphinico propionic acid. In mature canola seed, 37-55% of the TRR was identified as glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid and 12% of the TRR was associated with water soluble polysaccharides and proteins. In canola seed hulls, 50-59% of the TRR was identified as glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid.

The submitted study is marginally adequate to describe the nature of the residue in transgenic canola. The storage interval prior to analysis and extraction of whole plant and canola foliage (19 months) was not within the validated time interval (12 months). Seed and hull samples were analyzed using two HPLC systems (whole plant and foliage samples analyzed by system 1 only). Different levels of parent, N-acetyl glufosinate and 3-methylphosphinico propionic acid were observed depending on which HPLC system was used. No explanation for this difference was provided. Since adequate metabolism studies on transgenic field corn and soybean have been previously submitted (D211531 and D219069, M. Rodriguez, 7-Mar-1996) and the results from the canola study do not significantly differ from these studies, no additional data pertaining to the metabolism of glufosinate-ammonium in transgenic canola are required. The residues of concern in/on transgenic canola are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate.

Potatoes: A metabolism study has not been performed on a genetically unaltered root vegetable (potato). Since the metabolism of glufosinate ammonium is consistent in four diverse crop groups (lettuce [leafy vegetable], soybeans [legume vegetable], wheat [cereal grain] and apple [fruit]) the nature of residues in potatoes will be considered to be understood. The residues of concern in/on potatoes are glufosinate ammonium and 3-methylphosphinico propionic acid.

Animals: The nature of glufosinate ammonium residues in lactating goats and laying hens is considered to be understood. It was shown that glufosinate ammonium and its metabolite (3-methylphosphinico propionic acid) are largely excreted and do not accumulate to any great degree in animal tissues. The only identifiable compounds in feces, urine, milk, eggs and tissues were the parent and 3-methylphosphinico propionic acid. The residues of concern in commodities derived from ruminants and poultry are glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990).

Feed commodities derived from transgenic crops contain a second metabolite, N-acetyl glufosinate, which may lead to secondary residues of this compound in animal commodities. Feeding studies conducted on dairy cows and laying hens were submitted and reviewed as part of a glufosinate ammonium registration on transgenic field corn and soybeans (D211531 and D219069, M. Rodriquez, 7-Mar-1996). In these studies, dairy cows and hens were fed a diet consisting of 15% glufosinate ammonium and 85% N-acetyl glufosinate. Using the residues found in these feeding studies and the maximum theoretical dietary burden to ruminants and poultry, tolerances at the limit of quantitation were sufficient. Since an increase in ruminant tolerances was not necessary, it was decided that the current tolerance expression of glufosinate ammonium and 3-methylphosphinico propionic acid is adequate (inclusion of N-acetyl glufosinate ammonium was not necessary; D211531 and D219069, M. Rodriguez, 7-Mar-1996). Additionally, the tolerance expression for poultry commodities (new tolerance as a result of registration on transgenic soybeans and transgenic field corn) would include glufosinate ammonium and 3-methylphosphinico propionic acid (N-acetyl glufosinate should not be included; D232571, M. Rodriguez).

If any future petition results in a maximum theoretical dietary burden which requires milk, egg or tissue tolerances above the LOQ; the tolerance expression will be amended to include N-acetyl glufosinate.

Residue Analytical Methods (OPPTS GLN 860.1340)

Analytical methodology is available in PAM II for determination of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in genetically unaltered apples, bananas, grapes and tree nuts (HRAV-5A) and in milk, eggs and the tissues of ruminants and poultry (HRAV-12, also called BK/01/95). In transgenic crops a second metabolite, N-acetyl glufosinate, is present. Method AE-24, which is a variation of HRAV-5A, was developed for individual determination of the three compounds regulated in transgenic crops.

Several variations of HRAV-5A and AE-24 were used for quantitation of residues in the submitted field trials; all of which are adequate for data gathering purposes. Two of these methods, BK/04/95 (used for quantitation of residues in/on transgenic sugar beet commodities) and HRAV-24 (used for quantitation of residues in/on transgenic canola commodities), were submitted to the Analytical Chemistry Branch (ACB) for Petition Method Validation (D254830, T. Bloem, 1-Apr-1999). A brief description of a GC/MS confirmatory technique has also been submitted by the registrant.

ACB has not completed the validation procedure for either method. The petitioner has provided concurrent fortification data to demonstrate that BK/04/95 and HRAV-24 are adequate for data collection purposes. HED requires a successful petition method validation and the registrant will be

required to make any necessary modifications to the method resulting from petition method validation.

Multiresidue Method (OPPTS GLN 860.1360)

Glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate were not quantitatively recovered from any of the FDA Multiresidue Testing Protocols. This information has been forwarded to FDA (PP#8F3607, J. Garbus, 14-Aug-1988; PP#5F4578, M. Rodriguez, 10-Oct-1995).

Storage Stability Data (OPPTS GLN 860.1380)

The submitted storage stability study indicates that glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid are stable in transgenic sugar beet tops and roots for 24 months.

Previously submitted and reviewed storage stability data indicate that glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid are stable for 24 months in apples, corn grain and soybeans (PP#8F3607, J. Garbus, 8-Aug-1990). Glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate are stable for 12 months in transgenic soybean seed, forage and hay; for 3 months in soybean oil and meal; for 6 months in transgenic corn grain, fodder and forage; and for 3 months in eggs, liver, kidney and muscle (D211531 and D219069, M. Rodriguez, 7-Mar-1996).

These storage intervals are adequate to cover the submitted field trial data (excluding sugar beet processed commodities; see processed food section).

Meat and Milk, Poultry and Eggs (OPPTS GLN: 860.1480)

Two dairy cow and two poultry feeding studies have been previously submitted, reviewed and determined to be adequate: **(1)** dairy cows and poultry feed a diet containing a 3:1 mixture of glufosinate ammonium and 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990) and **(2)** dairy cows and poultry feed a diet containing 15% glufosinate ammonium and 85% N-acetyl glufosinate (D211531 and D219069, M. Rodriguez, 7-Mar-1996). Since the majority of the dietary burden to ruminants and poultry originates from transgenic crops, the feeding studies performed with N-acetyl glufosinate and glufosinate ammonium will be considered representative. Considering all registered and proposed uses, the maximum theoretical dietary burden to ruminants and poultry requires no adjustment to the currently established tolerances.

Crop Field Trials (OPPTS GLN 860:1500)

Transgenic Sugar Beets: The two submitted sugar beet field trial studies are acceptable. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate in/on transgenic sugar beet tops and roots treated with Liberty™ Herbicide at 1.0-1.3x the maximum proposed seasonal rate ranged from <0.10 - 1.30 ppm (tops) and <0.10 - <0.830 ppm (roots). HED concludes that based on the submitted field trial data, the appropriate tolerance in/on sugar beet tops and roots is 1.5 ppm and 0.9 ppm, respectively.

Transgenic Canola: The two submitted canola field trial studies are acceptable. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate in/on transgenic canola seed following a single application of glufosinate ammonium at 0.8-1.2x the maximum proposed seasonal rate ranged from <0.15 - <0.336 ppm. HED concludes that based on the submitted field trial data, the appropriate tolerance in/on canola seed of 0.4 ppm, is appropriate.

Potatoes: The submitted potato field trial study is acceptable. The combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in/on potatoes treated with Rely® Herbicide at 1.1x the maximum proposed seasonal rate ranged from <0.10 - <0.667 ppm. HED concludes that based on the submitted field trial data, the appropriate tolerance in/on potatoes is 0.8 ppm.

Processed Food/Feed (OPPTS GLN: 860.1520)

Transgenic Sugar Beet: Sugar beets treated with Liberty™ Herbicide at 7.2x the maximum proposed seasonal application rate were harvested and processed into pulp, molasses and sugar. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate did not concentrate in pulp or sugar but did concentrate 6.8x in molasses. Processed samples were stored for 3 months prior to analysis. No storage stability data for sugar beet pulp, molasses or sugar have been submitted. The maximum combined glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate residue expected in sugar beet molasses, based on the highest average field trial (HAFT; 0.719 ppm; Fayette, OH; MRID 44358603) and the 6.8x concentration factor, is 5.0 ppm.

HED will not be opposed to conditional registration of glufosinate ammonium on transgenic sugar beets. Unconditional registration may be granted upon validation of the three-month storage interval for the processed commodities (sugar, pulp and molasses). Pending submission and evaluation of this data, HED concludes that the appropriate sugar beet molasses tolerance is 5.0 ppm.

Transgenic Canola: Canola seed harvested 70 days after treatment with glufosinate ammonium at 0.8x, 1.5x and 3.0x the maximum proposed seasonal application rate, were processed into meal, oil and soapstock. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate did not concentrate in oil or soapstock but did concentrate 3.4x and 2.9x in toasted meal (average 3.2x). HED concludes that based on the highest field trial residue (<0.336 ppm; Indian Head, Sk; MRID 44358609) and 3.2x concentration factor, the appropriate canola meal tolerance is 1.1 ppm.

Potato: Potatoes harvested 9 days after a single treatment with glufosinate ammonium at 5.3x the maximum proposed single and seasonal application rate were processed into chips, flakes and peel. Glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid did not concentrate in potato peel but did concentrate 2.3x in potato chips and 3.0x in potato flakes. HED concludes that based on the HAFT (0.662 ppm;Lee, FL; MRID 44583901) and the concentration factors the appropriate potato flake/granule and potato chip tolerances are 2.0 ppm and 1.6 ppm, respectively.

Confined/Field Accumulation in Rotational Crops (OPPTS GLN: 860.1850 & 860.1900)

The submitted label indicates a 120-day plant back interval for wheat only. The label must be changed to indicate a 120-day plant back interval for all crops except wheat where a 70-day plant back interval is appropriate (D211531 and D219069, M. Rodriguez, 7-Mar-1996; P. Errico [RD], 6-May-1998).

International Harmonization of Tolerances

Codex currently has maximum residue limits (MRLs) for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents in/on potatoes and sugar beets at 0.5 and 0.05 ppm, respectively (no MRLs established for canola). Canada currently has MRLs for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid in/on potatoes and canola at 0.4 ppm and 3.0 ppm, respectively (no MRLs established for sugar beets). No glufosinate ammonium MRLs have been established in/on potatoes, sugar beets or canola in Mexico.

Since the Canadian MRL for canola seed is significantly greater than the appropriate US tolerance, harmonization is not possible. Since the appropriate US tolerance for sugar beets and potatoes are greater than the Canadian and Codex MRLs, harmonization is not possible.

Dietary Risk Analysis

A chronic and acute dietary exposure analysis, using the Dietary Exposure Evaluation Model (DEEM™), was completed (D257266, T. Bloem, 19-Jul-1999; Attachment 4). Both the acute and chronic DEEM™ analyses used consumption data from USDA's 1989-1992 nationwide Continuing Survey for Food Intake by Individuals (CSFII).

Acute: The acute dietary exposure analysis for females 13 - 50 (no acute dietary endpoint was identified for the general US population including infants and children) assumed tolerance level residues and 100% crop treated for all registered and proposed commodities (Tier 1 analysis). The most highly exposed population was females 13 - 50/nursing at 58% of the aPAD (95th percentile). Acute dietary food exposure to glufosinate ammonium is below HED's level of concern.

Table 4: Summary of Results from Acute DEEM™ Analysis for Glufosinate Ammonium

subgroups	exposure[1] (mg/kg/day)	% aPAD[2]
Females (13 - 50, preg., not nursing)	0.008179	39
Females (13 - 50, nursing)	0.012131	58
Females (13-19 yrs., not preg., not nursing)	0.008425	40
Females (20+ years, not preg., not nursing)	0.007086	34
Females (13-50 years)	0.007751	37

[1] 95th percentile exposures
[2] aPAD = 0.021 mg/kg/day

Chronic: The chronic dietary exposure analysis assumed tolerance level residues for all registered and proposed commodities. The weighted average percent crop treated was incorporated for all registered commodities (sweet corn maintained at 100%; Tier 2 analysis). The most highly exposed population was children 1-6 years old at 71% of the cPAD. Chronic dietary food exposure to glufosinate ammonium is below HED's level of concern.

Table 5: Summary of Results from Chronic DEEM™ Analysis for Glufosinate ammonium

subgroups[1]	exposure (mg/kg/day)	% cPAD[2]
U.S. Population (48 states)	0.002120	30
Non-Hispanic blacks	0.002246	32
Non-Hispanic/non-white/non-black	0.002256	32
Non-Hispanic whites	0.002132	31
Children (1-6 years)	0.004974	71
Females (13 - 50 nursing)	0.002035	29
Males 13-19 yrs	0.002449	35

[1] The subgroups listed above are the US Population and other general subgroups for which the %cPAD is greater than that of the US Population
[2] cPAD = 0.007 mg/kg/day

4.2.2 Water Exposure

The following information was provided by EFED (D250756 & D257381, E. L. Libelo, Attachment 5). At the present time, there are no surface or ground water monitoring data available.

Environmental Fate Assessment: Glufosinate ammonium is highly water soluble and stable to hydrolysis and photolysis. Aerobic soil, anaerobic soil and aerobic aquatic half-lives are 23, 56 and 35 days, respectively. The relatively short half-lives for glufosinate ammonium are such that a sustained concentration in surface water is not likely. Due to the high water solubility of glufosinate ammonium, it will reach ground water relatively quickly and thereby counteract the

degradation seen in surface water. No information pertaining to the environmental fate of the 3-methylphosphinico propionic acid was provided by the petitioner. Ground and surface water concentration estimates were generated using the highest registered and proposed application rate for glufosinate ammonium (apples; 1.5 lbs ai/application; 4.5 lbs ai/year), the SCI-GROW screening model for ground water (Tier 1), and the PRZM/EXAMS model for surface water (Tier 2).

ground water estimate:	1.16 µg/L
surface water estimates:	34.1 µg/L (1 day in 10 year maximum) 0.79 µg/L (36 year average daily concentration)

Drinking Water Risk (acute and chronic): Aggregate exposures are generally calculated by summing dietary (food and water) and residential exposures. If the aggregate exposure is less than the specified PAD, the exposure is not expected to be of concern. Since HED does not have ground and surface water monitoring data to calculate a quantitative aggregate exposure, DWLOCs were calculated. The DWLOC is the upper limit of a chemical's concentration in drinking water that will result in an acceptable aggregate exposure. The DWLOC is used as a point of comparison against model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have indirect regulatory impact through aggregate exposure and risk assessments.

To calculate the acceptable acute and chronic exposure to glufosinate ammonium in drinking water, the dietary food exposure estimate was subtracted from the appropriate PAD (only short-term residential exposure). A DWLOC was then calculated by using default body weights and drinking water consumption figures (70kg/2L (adult male), 60kg/2L (adult female) and 10kg/1L (infant/child)).

The estimated maximum and average concentration of glufosinate ammonium in ground and surface water are less than HED's DWLOC for glufosinate ammonium as a contribution to acute and chronic aggregate exposure (for all population subgroups). EFED believes that the SCI-GROW model underestimates the potential glufosinate ammonium concentration in ground water. The DWLOCs are a minimum of 17x greater than the SCI-GROW model estimates. Therefore, an adequate margin of safety is present. Tables 6 and 7 are summarizes of acute and chronic DWLOCs.

Table 6: Acute DWLOCs

Population Subgroup[1]	aPAD mg/kg/day	Food Exposure mg/kg/day	Maximum Water Exposure[2] mg/kg/day	DWLOC[3] ppb	SCI-GROW ppb	PRZM-EXAMS ppb
Females (13 – 50, nursing)	0.021	0.012131	0.008869	270	1.16	34.1

[1] highest exposed subgroup among females 13 - 50
[2] maximum water exposure (mg/kg/day) = 0.021 mg/kg/day - acute food exposure (mg/kg/day)
[3] DWLOC = [(maximum water exposure mg/kg/day)(body weight kg)/(water consumption liters)] * 1000

Table 7: Chronic (non-cancer) DWLOC

Population Subgroup[1]	cPAD mg/kg/day	Food Exposure mg/kg/day	Maximum Water Exposure[2] mg/kg/day	DWLOC[3] ppb	SCI-GROW ppb	PRZM-EXAMS ppb
US Population	0.007	0.002120	0.004880	170	1.16	0.79
Non-Hispanic blacks	0.007	0.002246	0.004754	170	1.16	0.79
Non-Hispanic/non-white/non-black	0.007	0.002256	0.004744	170	1.16	0.79
Non-Hispanic whites	0.007	0.002132	0.004868	170	1.16	0.79
Children 1-6 yrs	0.007	0.004974	0.002026	20	1.16	0.79
Females 13 - 50 nursing	0.007	0.002035	0.004965	150	1.16	0.79
Males 13-19 yrs	0.007	0.002449	0.004551	160	1.16	0.79

[1] The subgroups listed above are the following: (1) US Population, (2) the other general subgroups for which the %cPAD is greater than that of the US Population and (3) the most highly exposed population among infants and children, females, and males.
[2] maximum water exposure (mg/kg/day) = (0.007 mg/kg/day - acute food exposure, (mg/kg/day)); no residential exposure
[3] DWLOC = [(maximum water exposure mg/kg/day)(body weight kg)/(water consumption liters)] * 1000

4.3 Occupational Exposure

The worker exposure and risk assessment presented in this document are based on the Pesticide Handler Exposure Database Version 1.1 (PHED, Surrogate Exposure Guide, August 1998) unit exposure estimates for workers wearing long pants, long sleeves, gloves (no gloves for aerial applicators), and using open cab ground equipment, and closed cab aerial equipment. There are no chemical specific data available to determine the potential risks associated with the proposed uses of glufosinate ammonium on transgenic canola, sugarbeets, and for desiccation of conventional potato vines.

Table 8: Use Pattern and Formulation Information

Formulation Type, % ai	Equipment	Use Sites	Application rate range	Timing and frequency of applications	Comments
Liquid 18.19% ai	ground and aerial equipment	transgenic sugarbeets, canola	**sugarbeets:** 0.26 - 0.55 lb ai/acre; not to exceed 1.1 lbs ai/acre/growing season **canola:** 0.26 - 0.42 lb ai/acre; not to exceed 0.89 lbs ai/acre/growing season	**sugarbeets:** 3 X season; from the cotyledon stage up to 10 leaf stage; PHI= 60 days **canola:** 2 X season; from the cotyledon stage up to the early bolting stage repeat applications should be made when newly germinated weeds again reach 1 inch in height or diameter; PHI = 65 days	foliar active material with no soil-residual activity; rainfast 4 hrs. after application; to be applied to young, actively growing weeds
Liquid 11.3% ai		potatoes	0.38 lb ai/acre	apply at the beginning of natural senescence of potato vines; PHI= 9 days	

4.3.1 Handler

Exposure Assumptions: The exposure assessment is based on the crop with the highest application rate (sugarbeets) and the crop with the highest average farm size (canola), as a conservative scenario. Commercial mixer/loaders (for aerial applications), commercial applicators (groundboom and aerial), and farmers (groundboom) treating their own fields were chosen as the most conservative scenarios. The occupational exposure assessment is based on the assumptions listed in Table 9.

Table 9: Assumptions for Worker Exposure Assessments

Exposure Scenario[1]	Unit Exposure ug/lb ai[2]		Application rate (lb ai/A)	Acres/ Day[3]	Data source
	Dermal	Inhalation			
Mixer/Loader (aerial)	23	1.2	0.55	570	Unit exposures: Pesticide Handlers Exposure Database V1.1, Surrogate Exposure guide, August 1998. Estimates for all liquids, open mixing/loading: high confidence data Estimates for groundboom, open cab: medium confidence data Estimates for aerial/fixed-wing/closed cab/liquid: medium confidence data
Applicator (groundboom - open cab)	14	0.7	0.55	380	
Applicator (aerial - enclosed cockpits)	5	0.068	0.55	570	
Mixer/loader and applicator (groundboom)	37	1.9	0.55	190	Unit exposures were estimated by adding the M/L and applicator unit exposures

1 Handlers wearing long-sleeved shirt, long pants, and gloves (no gloves for aerial applicators)
2 Pesticide Handler Exposure Database Version 1.1 (PHED, Surrogate exposure Guide, August 1998)
3 Average canola farm is approximately 190 acres (United States 1997 Census of Agriculture, Table 42). Ground applicator assumed to treat 2 farms/day, aerial applicator assumed to treat 3 farms/day. The highest application rate and acreage from the proposed uses were used in this assessment.

Worker Exposure and Risk Assessment: Table 10 summarizes the worker exposure and risk estimates for commercial mixer/loaders, commercial applicators, and for farmers (m/l/a) treating their own fields. Short and intermediate-term exposures are expected for commercial applicators; only short-term exposures are expected for private applicators. Since workers are required to wear additional personal protective clothing (coveralls and protective eyewear) that are not accounted for in this assessment, the estimates of exposure are considered conservative.

Table 10: Occupational Exposure and Risk Estimates

Exposure Scenario	Unit Exposure (ug/lb ai)		Exposure[1] (mg/kg/day)			Short- & Intermediate - Term MOE[2]		
	Dermal	Inhalation	Dermal	Inhalation		Dermal	Inhalation	
				Short	Intermediate		Short	Intermediate
Mixer/ Loader	23	1.2	0.10	0.0054	0.0063	1000	1000	390
Applicator Groundboom - open cab	14	0.7	0.042	0.0021	0.0024	2400	3000	880
Applicator Aerial - enclosed cockpits	5	0.068	0.022	0.00031	0.00036	4600	20000	5800
Mixer/loader applicator (groundboom)	37	1.9	0.055	0.0028	0.0033	1800	2300	640

1 Exposure = Unit exposure × application rate × acres/day × 1/kg bw × .001mg/ug; 60 kg bw for short-term inhalation exposure, 70 kg bw for other exposures
2 Dermal NOAEL = 100mg/kg/day; Inhalation NOAEL = 6.3mg/kg/day and 2.1mg/kg/day for short-term exposure and intermediate- term exposures, respectively MOE = NOAEL ÷ Exposure; Level of concern = 100

The potential risks for occupational workers from short and intermediate-term exposures from the proposed uses of glufosinate ammonium on canola, sugarbeets, and potatoes do not exceed the Agency's level of concern. Chronic exposures are not expected from the proposed uses, therefore a risk assessment was not conducted.

4.3.2 Post-Application

There are no chemical-specific data available to determine the potential risks from post application activities associated with this proposed section 3 use of glufosinate ammonium. However, potential post-application exposures are not of concern, based on the use pattern, timing of applications, and the fact that planting and harvesting of the subject crops are mechanized. Most workers entering treated fields are likely to be performing low contact labor tasks such as mechanical incorporation and cultivation. Hoeing and scouting activities are also anticipated, but risks from these activities are not expected to exceed the Agency's levels of concern. For the purposes of the proposed use, reentry restrictions and personal protective clothing specified on the product label should provide adequate protection from the potential post-application exposures. Workers reentering treated fields before the required restricted entry interval are required to wear coveralls over short-sleeved shirts and short pants, chemical-resistant gloves, chemical resistant footwear and socks, and protective eyewear.

Restricted Entry Interval (REI): The interim restricted entry interval (REI) is 12 hours based on glufosinate ammonium's acute toxicity classification III for the dermal, inhalation, and ocular routes of exposure.

4.4 Residential Exposure

Glufosinate ammonium is registered for residential (outdoor, non-food) products as a non selective, postemergent herbicide. As such, it is primarily used as a spot treatment around trees, shrubs, fences, walks, patios, driveways, sidewalks, and flower beds. It is also registered for lawn renovation uses. There is no chemical specific data to assess exposures from the registered residential uses of glufosinate ammonium. The HED Exposure SAC considered these uses and recommended that the turf and garden scenarios, as specified in the Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments (18-DEC-1997), be used as a screening level assessment of the potential risks to homeowners from glufosinate ammonium use (see attachment 7, ***Minutes for Meeting of the Science Advisory Council for Exposure***).

4.4.1 Handler/Post-Application

The risk assessment was conducted using the following assumptions: dermal and inhalation unit exposure of 100 mg/lb ai and 30 ug/lb ai, respectively, maximum application rate of 1.4 lb ai/acre (product label), and a maximum area treated of 10,000 sq. ft. for the garden use scenario, 20,000 sq ft for the lawn renovation scenario, and 1,000 sq ft for "spot" lawn renovation scenario. Intermediate- and chronic-term residential exposures are not expected from the registered uses of glufosinate ammonium, therefore only short-term exposures were considered.

Table 11: Residential Handler Exposure and Risk Assessment

Scenario	Unit Exposure (mg/ lb ai)		Potential Dose Rate[1] (mg/kg/day)		Short -Term MOE [2]	
	Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
Garden use (low pressure hand wand)	100	0.030	0.46	1.4 E-4	*217*	45,000
Lawn renovation (full lawn; garden hose end sprayer)	30	0.0095	0.28	1.0 E-4	*360*	63,000
Lawn renovation (spot treatment; low pressure hand wand)	100	0.030	0.046	1.4 E-5	2200	450,000

[1] Potential Dose Rate (PDR) = Unit exposure x Maximum application rate (1.4 lbs ai/acre) x Maximum area treated (garden use:10,000sq ft; lawn renovation: 20,000sq ft for full lawn and 1,000sq ft for spot treatment) ÷ kg bw (70 kg bw and 60 kg bw for short-term dermal and inhalation exposure, respectively. (Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments and Appendix B (18-DEC-1997)

[2] Dermal NOAEL = 100 mg/kg/day; Inhalation NOAEL = 6.3 mg/kg/day for Short-term exposure; MOE = NOAEL/Exposure; Level of concern = 300

Table 12: Residential Post-Application Exposure and Risk Assessment [1]

Scenario	Transfer coefficient (cm^2/hr)	Potential Dose Rate [2] (mg/kg/day)	MOE [3]
Adult (garden use)	10,000	0.3	330
Children (garden use)	5,000	0.13	770
Adult (lawn renovation)	43,000	0.96	100
Children (lawn renovation)	8,700	0.91	110

[1] Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments and Appendix B 18-DEC-1998). DFR_0 = Application rate x fraction available as residue (20% for garden use, 5% for lawn use; based on a decision of the Science Advisory Council for Exposure, see Minutes for Meeting of the Science Advisory Council for Exposure dated August 5, 1999) x 4.54E8 ug/lb x 2.47E-8 acre/cm^2 = 3.14 ug/cm^2 for garden use; 0.78 for lawn use

[2] Potential post application dose rate= DFR x Transfer coefficient x Exposure time (garden use: 0.67 hr/ for adults, 0.33 hrs for children; lawn use: 2.0 hr) / BW (70 kg for adult, 39.1 for children (garden use) and 15 kg for children (lawn use) x 0.001mg/ug

[3] Dermal NOAEL = 100 mg/kg/day; MOE = NOAEL/Exposure; Level of concern = 300

These estimates indicate that the potential risks from homeowner uses of glufosinate ammonium exceed the Agency's level of concern. The Agency's level of concern is for MOEs below 300. The dermal MOEs for homeowners applying glufosinate ammonium for the garden use is 217. The dermal MOEs for postapplication exposures from lawn renovation uses are 100 and 110 for adults and children, respectively. These estimates are based on screening level assumptions and therefore should be considered conservative.

In looking at these risk estimates it should be kept in mind that: **(1)** residential use of nonselective herbicides is likely to occur as a "spot spray" in small turf areas with a high content of non-desirable

grasses or in areas that have been converted to some other uses such as vegetable or flower gardening. Lawn renovation treatment is recommended when 70% of the lawn is infested with undesirable lawn grasses (***Renovating your lawn, publication from Rutgers Cooperative Extension Service, N.J. Agricultural Experiment Station***). Therefore lawn renovation is considered a "last resort" treatment and a use pattern that is not likely to involve the average homeowner on a regular basis (scheduled treatments with selective herbicides to control undesirable weeds); **(2)** Information from Turfgrass Producers International (a not-for-profit trade association) indicates that "80% of nonselective herbicides production is used on new construction, with the remaining 20% going to golf courses, parks, sports fields, cemeteries, roadsides, etc. Exceptionally small amounts of turfgrass sod are used in lawn restoration projects"; **(3)** Information from AgrEvo indicates that sales of formulations containing glufosinate ammonium (Finale® Concentrate and Super Concentrate) sold to the homeowner lawn and garden market in 1998 represents a very small percentage of that for crops. It should also be considered that the SOP's assumptions for the garden scenario are based on a 10,000 sq ft "farm garden" which is not representative for the average homeowner. In addition, the lawn renovation scenario is based on transfer coefficients and assumptions used for regular lawn uses which are not necessarily applicable to lawn renovation uses and therefore, further overestimate the real potential risks.

5.0 AGGREGATE EXPOSURE AND RISK ASSESSMENT/CHARACTERIZATION

5.1 Acute Aggregate Risk

The acute dietary exposure analysis for females 13 - 50 (no acute dietary endpoint was identified for the general US population including infants and children) assumed tolerance level residues and 100% crop treated for all registered and proposed commodities (Tier 1 analysis). The most highly exposed population among females 13 - 50 was nursing females at 58% of the aPAD (95th percentile). The estimated glufosinate ammonium concentration in surface and ground water are less than HED's DWLOC (for all population subgroups). Acute aggregate exposure to glufosinate ammonium, as a result of all registered and proposed uses, is below HED's level of concern.

5.2 Short- and Intermediate-Term Aggregate Risk

Short- and intermediate-term aggregate risk assessments include average dietary exposure (food and water) and short- or intermediate-term dermal and inhalation exposures from residential uses. The dermal exposure estimates from the registered residential uses of glufosinate ammonium are above HED's level of concern (inhalation residential exposures were insignificant). According to HED policy (HED SOP 97.2), the residential dermal exposures cannot be aggregated with chronic dietary exposure because different endpoints were chosen for these exposure scenarios.

5.3 Chronic Aggregate Risk

There are no chronic residential exposure scenarios. Therefore, only food and water are included in the chronic aggregate risk. The chronic dietary exposure analysis assumed tolerance level residues for all registered and proposed commodities and incorporated the weighted average percent crop treated (BEAD, A. Halvorson, 15-Apr-1999) for all registered commodities (sweet corn maintained at 100% crop treated; Tier 2 analysis). For the most highly exposed subgroup (children, 1-6 years), 71% of the

cPAD is occupied by dietary (food) exposure. The estimated glufosinate ammonium concentrations in surface and ground water are less than HED's DWLOC (for all population subgroups). Chronic aggregate exposure to glufosinate ammonium, as a result of all registered and proposed uses, is below HED's level of concern.

5.4 Cancer Aggregate Exposure and Risk

Glufosinate ammonium has been classified as a **"not likely"** carcinogen according to the EPA *Proposed Guidelines for Carcinogen Risk Assessment*. Therefore, a cancer risk assessment is not necessary.

6.0 ACTIONS REQUIRED BY REGISTRANTS

6.1 Data Requirements

6.1.1 Toxicology Studies :

- Acute Neurotoxicity, Subchronic Neurotoxicity and Developmental Neurotoxicity Studies (Guidelines 81-8, 82-7 and 83-3; respectively)

6.1.2 Chemistry

- A Revised Section B (Liberty™, Rely®)
- Storage stability Study for Sugar Beet Processed Commodities (sugar, pulp and molasses; 3 months) (Guideline 860.1380)
- Petition Method Validation for Methods BK/04/95 (sugar beets) and HRAV-24 (canola). Validation of these methods has been requested (D254830, T. Bloem, 1-Apr-1999) but has not been completed. The petitioner has provided concurrent fortification data to demonstrate that BK/04/95 and HRAV-24 are adequate for data collection purposes. HED requires a successful petition method validation and the registrant will be required to make any necessary modifications to the method resulting from petition method validation.

6.1.3 Occupational/Residential: None

cc without attachments: PP#s 7404910 & 8F04997, Myrta Christian, Myron Ottley, Tom Bloem
RDI: M. Morrow (8-Sep-1999), RAB1 (6-Aug-1999), RARC (17-Aug-1999)
T. Bloem:806R:CM#2:(703)605-0217

END OF DOCUMENT

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

19-August-1999

Memorandum

Subject: PP#s 7F04910, 8F04997 - AgrEvo USA Company has Requested a Section 3 Registration for use of Glufosinate Ammonium (Liberty™ and Rely®) on Potatoes, Transgenic Sugar Beets and Transgenic Canola. **Amendment of 5-August-1999.** DB Barcodes D258420. Chemical # 128850. Case #s 289177, 290273. Submission #s S529287, S545114

From: Tom Bloem, Chemist TB
RAB1/HED (7509C)

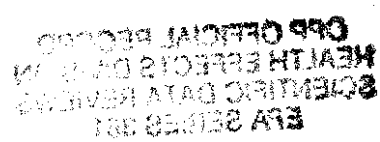
Through: Melba Morrow, DVM, Branch Senior Scientist MM for
George Kramer, Ph.D., Chemist
RAB1/HED (7509C)

To: Joanne Miller/Eugene Wilson (PM Team 23)
RD (7505C)

AgrEvo USA Company has requested a Section 3 registration for use of glufosinate ammonium on potatoes, transgenic sugar beets and transgenic canola. Information submitted by the petitioner pertaining to residue chemistry data requirements were evaluated and several deficiencies noted (D257629, D257628, T. Bloem, 9-Jul-1999). The current amendment is HED's review of information submitted by the petitioner addressing these deficiencies.

Executive Summary of Chemistry Deficiencies

- Revised Section B (conclusion 1b)
- Storage stability Study for Sugar Beet Processed Commodities (sugar, pulp and molasses; 3 months)
- Successful Petition Method Validation for Methods BK/04/95 (sugar beets) and HRAV-24 (canola)



RECOMMENDATIONS

There are no residue chemistry data requirements that would preclude a conditional registration of glufosinate ammonium on transgenic sugar beets, transgenic canola and potatoes. Unconditional registration may be granted upon submission and evaluation of the information specified in conclusions 1b, 2 and 4. HED concludes that the following tolerances, for the combined residues of glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents, are appropriate (the tolerances assume the requested changes to Section B have been made):

Sugar Beet, Top	1.5 ppm
Sugar Beet, Root	0.9 ppm
Sugar Beet, Molasses	5.0 ppm
Canola Seed	0.4 ppm
Canola, Meal	1.1 ppm
*Potato	0.8 ppm
*Potato, chip	1.6 ppm
*Potato, granules/flakes	2.0 ppm

*Tolerance expression for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents (non-transgenic crop).

A human-health risk assessment will be prepared as a separate document.

CONCLUSIONS

1a. The requested changes to the Rely® and Liberty™ labels have been made. The deficiencies identified in the original memo are resolved.

1b. The petitioner added information to the canola portion of the Liberty™ label allowing a higher application rate if the canola seed is retained for planting in the future. The Chemistry Science Advisory Committee discussed this issue and determined that canola grown for seed is a food use and therefore requires a tolerance (Chem SAC Minutes, 21-Jul-1999). The information pertaining to the higher use rate for canola grown for seed should be eliminated from the Liberty™ label. Additionally, the "Restrictions to the Directions for Use" section of the Liberty™ label for sugar beet and canola indicates application rates in ounces/acre. The units for application rates should be fluid ounces/acre. Finally, the restricted entry interval for workers should be increased from 12 to 24 hours on both the Rely® and Liberty™ labels (Occupational/Residential Exposure and Risk Assessment, D258415 and D258416, M. Christian, 6-Aug-1999). The petitioner should submit a revised Section B.

2. The deficiency related to a description of the confirmatory technique has been resolved. The Analytical Chemistry Branch (ACB) has not completed the validation procedures for methods BK/04/95 or HRAV-24. Given that the registrant has provided concurrent fortification data to demonstrate that BK/04/95 and HRAV-24 are adequate for data collection purposes and these methods are a modification of the current tolerance enforcement method, HED concludes that they are suitable enforcement methods to support tolerances associated with a conditional registration on potatoes, transgenic sugar beets and transgenic canola. As a condition of the registration, HED will require a successful petition method validation and the registrant will be required to make any necessary modifications to the method resulting from petition method validation.

3. A Section F, indicating the appropriate metabolites and tolerances for sugar beet, canola and potato commodities, has been submitted.

4. A storage stability study for Sugar Beet Processed Commodities (sugar, pulp and molasses; 3 months) is required. Pending submission and evaluation of this data, HED concludes that glufosinate ammonium and its metabolites do not concentrate in sugar beet pulp or sugar and the petitioners proposed sugar beet molasses tolerance of 5.0 ppm is appropriate.

DETAILED CONSIDERATIONS

Deficiency - Conclusions 2a, 2b and 2c (from D258075, T. Bloem, 28-Jul-1999)

2a The sugar beet portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that the maximum single application rate is 42 fluid ounces/acre (0.55 lbs ai/acre).

2b. The maximum seasonal application rate for canola is listed as 0.89 lbs ai/acre in the application timing section and 0.84 lbs ai/acre in the special notes section (0.89 lbs ai/acre will be assumed to be correct). The petitioner indicated that only the spring variety of canola has been genetically modified for tolerance to glufosinate ammonium. In Region 2, canola is only planted in the winter months (winter variety of canola) due to the unfavorable climate for canola in the summer. Therefore, the petitioner is not requesting registration of transgenic canola in Region 2. The canola portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that use of this product on transgenic canola in Region 2 is prohibited.

2c. Both the Rely® Herbicide and Liberty™ Herbicide labels should be amended to indicate a 120 day plant back interval for all crops except wheat where a 70 day plant back interval is appropriate.

Petitioner's Response: Submission of Revised Section B. The following information was added to the canola portion of the Liberty™ label, "Do not apply.....more than 120 ounces per acre of Liberty Herbicide for segregate control during seed production per growing season". This increased rate (1.56 lbs/acre/season) is addressed a second time in an added section titled "Rate Recommendation for Use in Canola Seed Propagation" which states the following:

> For the detection and control of susceptible canola "segregates" during canola seed production only, Liberty Herbicide may be applied at up to 40 fluid ounces (2.5 pints) per acre on canola from the cotyledon stage to the early bolting stage of the canola. Applications may be repeated, if necessary, up to three times in one growing season.
>
> Do not apply more than 120 ounces of product per acre to canola being grown for seed production in one growing season.

HED's Conclusions: The requested changes to the Rely® and Liberty™ labels have been made. The deficiencies identified in the original memo are resolved.

The petitioner added information to the canola portion of the Liberty™ label allowing a higher application rate if the canola seed is retained for planting in the future. The Chemistry Science Advisory Committee (Chem SAC) recently discussed the food/non-food status of canola grown for seed. Chem SAC determined the following (Chem SAC Minutes, 21-Jul-1999):

> With a large acreage crop for which the seed is a significant food item and the sole reason the crop is grown in the first place, the SAC does not believe it is practical to prevent all the seed harvested from the treated crop from being diverted to food use. We are concerned with the precedent that would be set if these uses were classified as non-food uses. Nonfood uses may then be sought on even larger crops such as wheat and corn. Our guidelines state that there is little chance of calling applications to crops grown for seed nonfood uses when the seed is a major RAC (e.g., grains, beans, peas). It was specifically pointed out today by one chemist that a wheat hybridizing agent was registered a few years ago as a food use and tolerances established. We will continue to take the position that applications to such crops grown for seed are food uses requiring a tolerance (or exemption from tolerance if permitted by toxicological considerations).

The information pertaining to the higher application rate for canola grown for seed should be eliminated from the Liberty™ label. Additionally, the "Restrictions to the Directions for Use" section of the Liberty™ label for sugar beet and canola indicates application rates in ounces/acre. The units for application rates should be fluid ounces/acre. Finally, the restricted entry interval for workers should be increased from 12 to 24 hours on both the Rely® and Liberty™ labels (Occupational/Residential Exposure and Risk Assessment, D258415 and D258416, M. Christian, 6-Aug-1999). The petitioner should submit a revised Section B.

Deficiency - Conclusion 5d (from D257629, D257628, T. Bloem, 9-Jul-1999)

5d. Given that the registrant has provided concurrent fortification data to demonstrate that BK/04/95 and HRAV-24 are adequate for data collection purposes and these methods are a modification of the current tolerance enforcement method, HED concludes that they are suitable enforcement methods to support tolerances associated with a conditional registration on potatoes, transgenic sugar beets and transgenic canola. As a condition of the registration, HED will require a successful petition method validation and the registrant will be required to make any necessary modifications to the method resulting from petition method validation. Additionally, a complete description of the GC/MS confirmatory technique should be submitted by the petitioner.

Petitioner's Response: The petitioner provided the instrument model and GC conditions along with mass spectra for the parent and two metabolites. This information was taken from the metabolism study performed on transgenic field corn (MRID 43515602).

HED's Conclusions: The deficiency related to a description of the confirmatory technique has been resolved. ACB has not completed the validation procedure for BK/04/95 or HRAV-24. Therefore, the petitioner has not submitted a final version of these methods.

Deficiency - Conclusions 9f, 9i, 10c and 10i (from D257629, D257628, T. Bloem, 9-Jul-1999)

9f. HED concludes that based on the submitted field trial data, the appropriate tolerance in/on sugar beet tops and roots, as result of the application of glufosinate ammonium as defined in this petition, is 1.5 ppm and 0.9 ppm, respectively. The petitioner must submit a revised Section F proposing a 1.5 ppm tolerance in/on sugar beet tops and a 0.9 ppm tolerance in/on sugar beet roots for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

9i. HED concludes that based on the submitted field trial data, the appropriate tolerance in/on potatoes, as result of the application of glufosinate ammonium as defined in this petition, is 0.8 ppm. The petitioner must submit a revised Section F proposing a 0.8 ppm tolerance in/on potatoes for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

10c. HED concludes that the appropriate tolerance in/on canola meal, as a result of the application of glufosinate ammonium to canola as defined in this petition, is 1.1 ppm. The petitioner must submit a revised Section F proposing a canola meal tolerance of 1.1 ppm for the combined residues of glufosinate ammonium and its metabolites N-acetyl glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

10i. HED concludes that the appropriate tolerance in/on potato chips and potato granuales/flakes, as a result of the application of glufosinate ammonium to potatoes as defined in this petition, is 1.6 ppm and 2.0 ppm, respectively. The petitioner must submit a revised Section F proposing a potato chip tolerance of 1.6 ppm and a potato granule/flake tolerance of 2.0 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

Petitioner's Response: The petitioner submitted a revised Section F.

HED's Conclusions: The revised Section F indicates the appropriate metabolites and tolerances. These deficiencies have been resolved.

Deficiency - Conclusions 9f, 9i, 10c and 10i (from D257629, D257628, T. Bloem, 9-Jul-1999)

10f. HED will not be opposed to conditional registration of glufosinate ammonium on transgenic sugar beets. Unconditional registration may be granted upon validation of the three month storage interval for the processed commodities (sugar, pulp and molasses). Pending submission and evaluation of this data, HED concludes that the petitioners proposed sugar beet molasses tolerance of 5.0 ppm is appropriate.

Petitioner's Response: no response

HED's Conclusions: The requested information has not been provided. The deficiency remains outstanding.

cc: PP 7F04910 & 8F04997, T. Bloem (RAB1)
RDI: K. Whitby (19-Aug-1999), G. Kramer (19-Aug-1999), RAB1 Chemists (19-Aug-1999)
T. Bloem:806R:CM#2:(703)-605-0217

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

28-July-1999

MEMORANDUM

Subject: PP#s 7F04910, 8F04997 - Amendment to the Glufosinate Ammonium **Evaluation of Residue Data and Analytical Methods** Memorandum (D257629 & D257628, T. Bloem, 9-Jul-1999). DP Barcode D258075. Chemical # 128850. Case # 289177. Submission # S529287.

From: Tom Bloem, Chemist TB
RAB1/HED (7509C)

Through: Melba Morrow, DVM, Branch Senior Scientist
RAB1/HED (7509C)

To: Joanne Miller/Eugene Wilson (PM Team 23)
RD (7505C)

Several mistakes, related to calculation of application rates, were identified in the **Evaluation of Residue Data and Analytical Methods** memorandum (D257629 & D257628, T. Bloem, 9-Jul-1999). The "Special Notes" section of the Liberty™ label for sugar beet and canola indicates that the maximum seasonal rate for sugar beets is 84 ounces/acre and for canola is 64 ounces/acre. The units on the application rates should be 84 and 64 fluid ounces/acre. As a results, the application rates specified in Conclusions 2a and 2b (page 3) and OPPTS GLN 860.1200 Directions for Use Section (page 12) are incorrect. These section should read as indicated below (bolded text indicates where a change was made). The miscalculation of the application rates as no bearing on any other conclusion in the **Evaluation of Residue Data and Analytical Methods** memorandum.

OPPTS GLN 860.1200: Directions for Use

The petitioner is requesting registration of Liberty™ Herbicide (18.19% glufosinate ammonium; 1.67 lbs ai/US gallon; EPA Reg. No. 45639-199) for use on the transgenic varieties of sugar beet and canola and Rely® Herbicide (11.33% glufosinate ammonium; 1.00 lbs ai/US gallon; EPA Reg. No. 45639-187) for use in potato vine dessication. Both products are water-soluble and applied as a foliar spray. The Liberty™ label indicates that a 120 day interval from the last application is required prior to planting wheat and grazing treated crop or cut for hay is prohibited.

Sugar Beets: Applications of Liberty™ Herbicide may be made from the cotyledon stage up to the 10 leaf stage. Maximum recommended single application rate is **0.55 lbs ai/acre**. A maximum of **1.1 lbs ai/acre** can be applied per season. Application can be made with ground (controlled droplet application equipment or air assisted spray equipment; minimum of 10 gallons of water/acre) or aerial (minimum of 5 gallons of water/acre) equipment. The label specifies a 60 day pre-harvest interval (PHI).

Canola: Applications of Liberty™ Herbicide may be made from the cotyledon stage up to the early bolting stage (at this stage the plant has at least 6 leaves). A maximum of two applications per season is allowed with the total seasonal rate not to exceed **0.89 lbs ai/acre**. Application can be made with ground (controlled droplet application equipment or air assisted spray equipment; minimum of 10 gallons of water/acre) or aerial (minimum of 5 gallons of water/acre) equipment. The label specifies a 65 day PHI.

Potato: Application of Rely® Herbicide is recommended at the beginning of natural vine senescence. The product is to be applied at a rate of 0.375 lbs ai/acre in 20-100 gallons of water per acre with ground equipment or in 5-10 gallons of water per acre with aerial equipment. The label specifies a 9 day PHI. Potatoes grown for seed stock are not to be treated.

Conclusion: The sugar beet portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that the maximum single application rate is 42 fluid ounces/acre (**0.55 lbs ai/acre**).

The maximum seasonal application rate for canola is listed as **0.89 lbs ai/acre** in the application timing section and **0.84 lbs ai/acre** in the special notes section (**0.89 lbs ai/acre** will be assumed to be correct). The petitioner indicated that only the spring variety of canola has been genetically modified for tolerance to glufosinate ammonium. In Region 2, canola is only planted in the winter months (winter variety of canola) due to the unfavorable climate for canola in the summer. Therefore, the petitioner is not requesting registration of transgenic canola in Region 2. The canola portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that use of this product on transgenic canola in Region 2 is prohibited.

Both the Rely® Herbicide and Liberty™ Herbicide labels should be amended to indicate a 120 day plant back interval for all crops except wheat where a 70 day plant back interval is appropriate.

cc: PP 7F04910 & 8F04997, T. Bloem (RAB1)
RDI: M. Morrow (28-Jul-1999)
T. Bloem:806R:CM#2:(703)-605-0217

PP#9F5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

9-July-1999

MEMORANDUM

Subject: PP#s 7F04910, 8F04997 - AgrEvo USA Company has Requested a Section 3 Registration for use of Glufosinate Ammonium (Liberty™ and Rely®) on Potatoes, Transgenic Sugar Beets and Transgenic Canola. **Evaluation of Residue Data and Analytical Methods.** DP Barcodes D257629, D257628. Chemical # 128850. Case #s 289177, 290273. Submission #s S529287, S545114

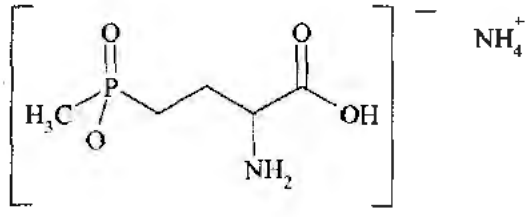
From: Tom Bloem, Chemist
RAB1/HED (7509C)

Through: Melba Morrow, DVM, Branch Senior Scientist
George Kramer, Ph.D., Chemist
RAB1/HED (7509C)

To: Joanne Miller/Eugene Wilson (PM Team 23)
RD (7505C)

AgrEvo USA Company has requested a Section 3 registration for use of glufosinate ammonium on potatoes, transgenic sugar beets and transgenic canola. Review of the metabolism studies were initially conducted by Dynamac. The Dynamac review has undergone secondary review by RAB1 and has been revised to reflect current division policies.

glufosinate ammonium (ammonium-DL-homoalanin-4-yl(methyl) phosphinate)



BACKGROUND

Glufosinate-ammonium is a racemic mixture of the D- and L-isomers; only the L-isomer is herbicidally active. The compound is a non-selective herbicide and acts as a inhibitor of glutamine synthetase which leads to poisoning of the plant by ammonia. Glufosinate-ammonium is currently registered for use on both transgenic and non-transgenic crops. Transgenic plants contain a gene (phosphiothrion-acetyl-transferase) which enables the plant to metabolize the herbicidally active moiety of glufosinate-ammonium into a N-acetyl glufosinate (2-acetamido-4-methylphosphinico-butanoic acid; which is not herbicidally active). This metabolite is found only in transgenic plants. The petitioner is proposing the establishment of permanent tolerances for the combined residues of glufosinate ammonium and its metabolites 2-acetamido-4-methylphosphinico butanoic acid and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents in/on the following commodities:

Beet, sugar, root	0.7 ppm
Beet, sugar, tops (leaves)	1.3 ppm
Beet, sugar, molasses	5.0 ppm
Canola, seed	0.4 ppm
Canola, meal	2.0 ppm
*Potato	0.4 ppm
*Potato, processed	1.0 ppm
*Potato, flakes	1.3 ppm

** tolerance for combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid (non-transgenic crop)*

Time-limited tolerances, with an expiration date of July 13, 1999, have been established for residues of glufosinate-ammonium and its metabolite, 3-methylphosphinico propionic acid, in/on almond hulls, apples, grapes, the tree nuts group, eggs, milk, and the fat, meat, and meat byproducts of ruminants and poultry [40 CFR §180.473(a)]. An import tolerance with an expiration date of January 18, 2000 has been established for combined residues of glufosinate-ammonium and its metabolite, 3-methylphosphinico propionic acid, expressed as glufosinate acid equivalents, in/on bananas [40 CFR §180.473(b)]. Time-limited tolerances, with an expiration date of July 13, 1999, have been established for residues of glufosinate-ammonium and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico propionic acid, in/on aspirated grain fractions, field corn grain, forage, and stover, soybeans, and soybean hulls derived from transgenic field corn and transgenic soybeans [40 CFR §180.473(c)]. A Section 18 request from Wisconsin for use of glufosinate ammonium on transgenic sweet corn has been approved (4.0 ppm tolerance established for residues of glufosinate-ammonium and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico propionic acid expressed as glufosinate acid equivalents). Tolerances were established on a time-limited basis due to a lack of a carcinogenicity study.

The following terms are used interchangeably throughout this document:

glufosinate ammonium = HOE 039866
N-acetyl glufosinate = 2-acetamido-4-methylphosphinico-butanoic acid, HOE 099730, HOE 085355
3-methylphosphinico propionic acid = HOE 061517, MP-propionic acid

EXECUTIVE SUMMARY OF CHEMISTRY DEFICIENCIES

- Revised Section B (Liberty™ and Rely®)
- Revised Section F (transgenic canola, transgenic sugar beet and potato)
- Storage Stability for Sugar Beet Processed Commodities (3 months)
- Analytical Chemistry Branch Validation of Proposed Tolerance Enforcement Methods
- Description of GC/MS Confirmatory Method

CONCLUSIONS

OPPTS GLN 830 Series: Product Properties

1. Product chemistry data for glufosinate ammonium has been submitted, reviewed and found acceptable. No additional product chemistry data is necessary for this petition (PP#8F3607, J. Garbus, 14-Oct-1988 and 8-Aug-1990).

OPPTS GLN 860.1200: Directions for Use

2a. The sugar beet portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that the maximum single application rate is 42 fluid ounces/acre (0.48 lbs ai/acre).

2b. The maximum seasonal application rate for canola is listed as 0.77 lbs ai/acre in the application timing section and 0.73 lbs ai/acre in the special notes section (0.77 lbs ai/acre will be assumed to be correct). The petitioner indicated that only the spring variety of canola has been genetically modified for tolerance to glufosinate ammonium. In Region 2, canola is only planted in the winter months (winter variety of canola) due to the unfavorable climate for canola in the summer. Therefore, the petitioner is not requesting registration of transgenic canola in Region 2. The canola portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that use of this product on transgenic canola in Region 2 is prohibited.

2c. Both the Rely® Herbicide and Liberty™ Herbicide labels should be amended to indicate a 120 day plant back interval for all crops except wheat where a 70 day plant back interval is appropriate.

OPPTS GLN 860.1300: Nature of the Residue - Plants

3a. ***Sugar Beet:*** The qualitative nature of glufosinate ammonium residues in transgenic sugar beets is adequately understood. Total radioactive residues (TRR) were 2.05 ppm in tops and 0.93 ppm in roots harvested 146 days following the last of 2 applications of [C^{14}]glufosinate-ammonium at 0.54 lbs ai/acre (total application rate 1.07 lbs ai/acre, 1.1x the maximum proposed single and seasonal application rates). Samples of sugar beet commodities were also collected at shorter preharvest intervals (PHIs); TRR were 20.08 ppm in tops and 2.01 ppm in roots collected 1 hour after the second application and were 12.26 ppm in tops and 6.75 ppm in roots collected 21 days after the second application.

In sugar beet tops and roots (all PHIs), 93-98% of the TRR was identified. The N-acetyl glufosinate metabolite was the major residue in all sugar beet top and root samples (55.2-67.9% TRR), except 0-day PHI tops where glufosinate ammonium accounted for 84.6% of the TRR (N-acetyl glufosinate accounted for 13.4% of the TRR). Glufosinate-ammonium accounted for 19.1-41.8% of the TRR in all other sugar beet top and root samples. 3-Methylphosphinico propionic acid was identified at low levels in all sugar beet samples (0.4-6.0% TRR). One additional metabolite, 2-methylphosphinico acetic acid, was identified in 146 day PHI tops at 0.07% TRR.

The current tolerance expression for commodities derived from transgenic crops includes the major residues identified in the sugar beet metabolism study and is adequate for commodities derived from transgenic sugar beet. The residues of concern in/on transgenic sugar beets are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate.

3b. ***Canola:*** Total radioactive residues (TRR) were 0.021-0.064 ppm in foliage, 0.134-0.220 ppm in roots, 0.076-0.263 ppm in hulls, and 0.045-0.109 ppm in seed harvested 120 days (at maturity) following a single application of [^{14}C]glufosinate-ammonium at 0.67 lbs ai/acre (0.9x the maximum proposed seasonal rate). Samples of canola commodities were also collected at shorter PHIs; TRR were 144.578 ppm in the entire plant collected at 1-hour PHI, and were 3.207 and 5.343 ppm in foliage, and 3.807 and 5.192 ppm in roots collected at 21-day PHI.

In the whole plant harvested 1 hour posttreatment, the parent accounted for the majority of the radioactivity (72.9% TRR, 105.4 ppm); N-acetyl-glufosinate was identified at 18.2% of the TRR (26.3 ppm). In foliage harvested 21 days posttreatment, the major residue was N-acetyl-glufosinate (60.2% TRR, 3.22 ppm); the parent was present at 20.7% of the TRR (1.11 ppm) and a small amount of 3-methylphosphinico propionic acid was identified (6.7% TRR, 0.358 ppm).

In mature canola seed and hulls (0.109 ppm and 0.263 ppm, respectively), 40-58% of the TRR was identified (the remainder of the extracted radioactivity was described as unknown metabolites equivalent to the LOD). Glufosinate-ammonium and 3-methylphosphinico propionic acid were the major residues identified, accounting for 5.0-44.8% of the TRR (0.007-0.118 ppm). The N-acetyl-glufosinate metabolite was a minor residue accounting for 1.1-13.9% of the TRR (0.001-0.037 ppm). In canola seed, radioactive residues associated with water-soluble polysaccharides and/or proteins accounted for 12.4% of the TRR (0.014 ppm).

The submitted study is marginally adequate to describe the nature of the residue in glufosinate tolerant canola. The test substance was applied at less than 1x the maximum proposed seasonal rate which resulted in low levels of radioactivity in canola seed, making identification of residues difficult. The storage interval prior to analysis and extraction of whole plant and canola foliage (19 months) were not within the validated time interval (12 months). Seed and hull samples were analyzed using HPLC systems 1 and 2 (whole plant and foliage samples analyzed by system 1 only). Different levels of parent, N-acetyl glufosinate and 3-methylphosphinico propionic acid were observed depending on which system was used. No explanation for this difference was provided. Since adequate metabolism studies on the transgenic varieties of field corn and soybeans have been previously submitted (D211531 and D219069, M. Rodriguez, 7-Mar-1996) and the results from the canola study do not significantly differ from these studies, no additional data pertaining to the metabolism of glufosinate-ammonium in transgenic canola are required. The residues of concern in/on transgenic canola are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate.

3c. ***Potato:*** The nature of the residue is considered to be understood in genetically unaltered lettuce, soybeans, corn, apples and wheat. After application of ^{14}C glufosinate ammonium to the nutrient medium (water or soil) in which these crops were grown, only one labeled metabolite could be identified, 3-methylphosphinico propionic acid (parent was not found). HED concluded that the residues to be regulated in commodities derived from genetically unaltered lettuce, soybeans, corn, apples and wheat are glufosinate ammonium and 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990).

A metabolism study has not been performed on a root vegetable (potato). Since the metabolism of glufosinate ammonium is consistent in four diverse crops groups (lettuce [leafy vegetable], soybeans [legume vegetable], wheat [cereal grain] and apple [fruit]) the nature of glufosinate ammonium residues in potatoes will be considered to be understood. The residues of concern in/on potatoes are glufosinate ammonium and 3-methylphosphinico propionic acid.

OPPTS GLN 860.1300: Nature of the Residue - Animals

4. The nature of glufosinate ammonium residues in lactating goats and hens is considered to be understood. It was shown that glufosinate ammonium and its metabolite (3-methylphosphinico propionic acid) are largely excreted and do not accumulate too any great degree in animal tissues. The only identifiable compounds in feces, urine, milk, eggs and tissues were the parent and 3-methylphosphinico propionic acid. HED concluded that the residues of concern in commodities derived from ruminants and poultry are glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990).

   Transgenic field corn, soybeans, canola and sugar beets contain a second metabolite, N-acetyl glufosinate, which may lead to secondary residues of this compound in animal commodities. Feeding studies conducted on dairy cows and laying hens were submitted and reviewed as part of glufosinate ammonium registration on transgenic field corn and soybeans. In these studies, dairy cows and hens were feed a diet consisting of glufosinate ammonium and N-acetyl glufosinate. It was determined, that the tolerance expression for poultry (new tolerance as a result of registration on transgenic soybeans and transgenic field corn) should include glufosinate ammonium and 3-methylphosphinico propionic acid (N-acetyl glufosinate should not be included; D232571, M. Rodriguez). Additionally, it was determined that the currently established egg, milk, and fat, meat, and meat byproducts tolerances on cattle, goats, hogs, horses, poultry, and sheep were adequate (D211531 and D219069, M. Rodriguez, 7-Mar-1996).

OPPTS GLN 860.1340: Residue Analytical Method

5a. Analytical methodology is available in PAM II for determination of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in genetically unaltered apples, bananas, grapes and tree nuts (HRAV-5A) and in milk, eggs and the tissues of ruminants and poultry (HRAV-12, also called BK/01/95). Method HRAV-5A employs extraction of glufosinate ammonia and its metabolite 3-methylphosphinico propionic acid from a 25 gram homogenized sample with water. The aqueous extract is filtered and subjected to anion-exchange chromatography for removal of interfering compounds. The residues are eluted from the resin with formic acid and derivatized by refluxing with trimethylorthoacetate. The derivatized residues are cleaned up on a silica gel column and quantified by GC/FPD. Concentrations are expressed in terms of glufosinate free acid equivalents.. Method HRAV-12 (used to determine residue levels in animal matrices) is similar to the plant method except for an addition step. Water extracts of tissues are diluted with acetone to precipitate protein, centrifuged and then subjected to anion ion-exchange chromatography.

5b. In transgenic crops a second metabolite, N-acetyl glufosinate, is present. Since glufosinate ammonium and N-acetyl glufosinate are derivatized to the same compound, HRAV-5A does not distinguish between these two compounds. A second method, AE-24, was developed for individual determination of the three compounds regulated in commodities derived from transgenic crops. Method AE-24 is a modification of HRAV-5A in that following anion exchange, cation exchange is performed. Two fractions are collected from the cation ion exchange column. One fraction contains N-acetyl glufosinate and MP propionic acid and the second fraction contains glufosinate ammonium. Each fraction is derivatized by refluxing with trimethylorthoacetate, cleaned up on a silica gel column and quantified by GC/FPD. All compounds are quantified in terms of glufosinate free acid equivalents.

5c. Several variations of these two methods were used for quantitation of residues in the submitted field trials; all of which are adequate for data gathering purposes. Two of these methods, BK/04/95 (used for quantitation of residues in/on transgenic sugar beet commodities) and HRAV-24 (used for quantitation of residues in/on transgenic canola commodities), were submitted to the Analytical

Chemistry Branch (ACB) for Petition Method Validation (D254830, T. Bloem, 1-Apr-1999). Method BK/04/95 is similar to the current analytical enforcement method HRAV-5A but with modifications for application to a root crop. Method HRAV-24, which employs the cation exchange fractionation procedure (cation exchange procedure has not undergone Agency validation), was submitted to ACB for validation.

5d. Given that the registrant has provided concurrent fortification data to demonstrate that BK/04/95 and HRAV-24 are adequate for data collection purposes and these methods are a modification of the current tolerance enforcement method, HED concludes that they are suitable enforcement methods to support tolerances associated with a conditional registration on potatoes, transgenic sugar beets and transgenic canola. As a condition of the registration, HED will require a successful petition method validation and the registrant will be required to make any necessary modifications to the method resulting from petition method validation. Additionally, a complete description of the GC/MS confirmatory technique should be submitted by the petitioner.

OPPTS GLN 860.1360: Multiresidue Method

6. Glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate were not quantitatively recovered from any of the FDA Multiresidue Testing Protocols. This information has been forwarded to FDA (PP#8F3607, J. Garbus, 14-Aug-1988; PP#5F4578, M. Rodriguez, 10-Oct-1995).

OPPTS GLN 860.1380: Storage Stability Data

7. The submitted storage stability study indicates that glufosiante ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid are stable in transgenic sugar beet tops and roots for 24 months.

   Previously submitted and reviewed storage stability data indicate that glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid are stable for 24 months in apples, corn grain and soybeans (PP#8F3607, J. Garbus, 8-Aug-1990). Additional storage stability data indicate that glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate are stable for 12 months in transgenic soybean seed, forage and hay; for 3 months in soybean oil and meal; for 6 months in transgenic corn grain, fodder and forage; and for 3 months in eggs, liver, kidney and muscle (D211531 and D219069, M. Rodriguez, 7-Mar-1996).

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

8. Two dairy cow and two poultry feeding studies have been previously submitted, reviewed and determined to be adequate: **(1)** dairy cows and poultry feed a diet containing a 3:1 mixture of glufosinate ammonium and 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990) and **(2)** dairy cows and poultry feed a diet containing 15% glufosinate ammonium and 85% N-acetyl glufosinate (D211531 & D211531, M. Rodriguez, 7-Mar-1996). Two feeding studies were performed on dairy cows and poultry due the different residues present in transgenic (principally N-acetyl glufosinate followed by glufosinate ammonium) and non-transgenic crops (principally 3-methylphosphinico propionic acid). Since the majority of the dietary burden to ruminants and poultry originates from transgenic crops, the feeding studies performed with N-acetyl glufosinate and glufosinate ammonium will be considered representative.

   Considering all registered and proposed crops the maximum theoretical dietary burden is 14.55 ppm for beef cattle (aspirated grain fractions, corn field forage, cannery waste), 14.22 ppm for dairy cattle (aspirated grain fractions, corn field forage, cannery waste, molasses), 2.62 ppm for poultry (soybean

hulls, soybean meal, soybean seed, canola meal) and 8.07 ppm for swine (aspirated grain fractions, canola meal, potato culls). Using these dietary burdens and the feeding studies performed with N-acetyl glufosinate and glufosinate ammonium, no adjustment in ruminant and poultry tolerances are necessary.

OPPTS GLN 860.1500: Crop Field Trials

9a. ***Canola:*** The petitioner has requested a canola seed tolerance of 0.4 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate. The petitioner indicated that only the spring variety of canola has been genetically modified for tolerance to glufosinate ammonium. In Region 2, canola is only planted in the winter months (winter variety of canola) due to the unfavorable climate for canola in the summer. Therefore, the petitioner is not requesting registration for application of glufosinate ammonium to transgenic canola in Region 2.

9b. Two canola field trial studies conducted in Canada were submitted (MRID 443586-08 & -09). The field portion of MRID 443586-08 was not conducted according to GLP standards. The deficiencies which lead to nonconformance were not provided. Information pertaining to the application date, method, equipment, volume, timing and rate were provided. Therefore, the factors that lead to nonconformance with GLP standards will be considered minor and the study is acceptable. The field trial data conducted as part of MRID 443586-09 is also acceptable.

The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate in/on transgenic canola seed following a single application of glufosinate ammonium at 0.9x or 1.3x the maximum proposed seasonal use rate ranged from <0.15 - <0.336 ppm (treated at 3-7 leaf stage; PHI = 57 - 83 days).

9c. According to Table 5 of OPPTS GLN 860.1500, a total of 8 trials conducted in Regions 2 (n=1, not necessary for this petition), 5 (n=2), 7 (n=2) and 11 (n=3) are suggested. The Canadian field trial data submitted with this petition can be applied to the following Regions (HED SOP 98_2); Region 7 (n=2) and Region 14 (n=12; Region 14 is unique to Canada). The issue of how to apply canola field trial data from Region 14 to a US Registration was brought to Chem SAC. B. Schneider gathered information on canola production in the US and Canada and concluded that the majority of US canola is grown in ND, MN, MT, WA and SD. Generally within these states the northern most counties are the highest producing areas of the state. The canola production in Region 11 has decreased and increased in Regions 5 and 7 since the guidelines were written. The SAC agreed on accepting the Canadian canola field trials for glufosinate ammonium due to the similarities between the US canola production areas and Region 14 (Minutes of 17-Jun-1999 ChemSAC meeting). Geographical distribution of the submitted field trials is adequate for establishment of a tolerance in/on canola. HED concludes that based on the submitted field trial data, the petitioners proposed tolerance of 0.4 ppm is appropriate.

9d. ***Sugar Beet:*** The petitioner has requested a sugar beet top tolerance of 1.3 ppm and a sugar beet root tolerance of 0.7 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

9e. The two submitted sugar beet field trial studies are adequate (MRIDs 443586-02 and -03). The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate in/on transgenic sugar beet tops and roots treated with Liberty™ Herbicide at 1.1x - 1.5x the maximum proposed seasonal use rate ranged from <0.10 -1.30 ppm (tops) and <0.10 -

<0.830 ppm (roots). Pre-harvest intervals ranged from 41 - 139 days. Only 4 of the 14 field trials had a pre-harvest interval less than 80 days (label specifies a PHI = 60 days). The label indicates that the product may be applied from the cotyledon to 10 leaf stage of the sugar beet. The final application for all field trials was either at the 8 or 10 leaf stage and samples were harvested when the crop reached maturity. Since crop harvest was governed by crop development and the increased PHIs were counteracted in some cases by application rates 1.5x the maximum proposed rate, HED concludes that the field trial data are acceptable. Geographical distribution of the submitted field trials is adequate for establishment of a tolerance in/on sugar beets.

9f. HED concludes that based on the submitted field trial data, the appropriate tolerance in/on sugar beet tops and roots, as result of the application of glufosinate ammonium as defined in this petition, is 1.5 ppm and 0.9 ppm, respectively. The petitioner must submit a revised Section F proposing a 1.5 ppm tolerance in/on sugar beet tops and a 0.9 ppm tolerance in/on sugar beet roots for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

9g. ***Potato:*** The petitioner has requested a potato tolerance of 0.4 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

9h. The submitted potato field trial study is adequate (MRID 44583901). The combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in/on potatoes treated with Rely® Herbicide at 1.1x the maximum proposed seasonal use rate (PHI = 9-10 days) ranged from <0.10 - <0.667 ppm. Geographical distribution of the submitted field trials is adequate for establishment of a tolerance in/on potatoes.

9i. HED concludes that based on the submitted field trial data, the appropriate tolerance in/on potatoes, as result of the application of glufosinate ammonium as defined in this petition, is 0.8 ppm. The petitioner must submit a revised Section F proposing a 0.8 ppm tolerance in/on potatoes for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

OPPTS GLN 860.1520: Processed Food/Feed

10a. ***Canola:*** The petitioner has requested a canola meal tolerance of 2.0 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

10b. The submitted canola processing study is adequate (MRID 44358610). Canola seed harvested 70 days after treatment with glufosinate ammonium at 0.67, 1.3 or 3.3 lbs ai/acre/application (0.9x, 1.7x and 4.3x the maximum seasonal application rates; treated at 4-6 leaf stage) was processed into meal, oil and soapstock. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate did not concentrate in oil or soapstock but did concentrate 3.4x and 2.9x in toasted meal (average 3.2x).

The highest field trial for canola seed was <0.336 ppm (Indian Head, Sk; MRID 44358609). The maximum combined glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate residue expected in/on transgenic canola meal, based on the highest field trial and the 3.2x concentration factor, is 1.1 ppm.

10c. HED concludes that the appropriate tolerance in/on canola meal, as a result of the application of glufosinate ammonium to canola as defined in this petition, is 1.1 ppm. The petitioner must submit a revised Section F proposing a canola meal tolerance of 1.1 ppm for the combined residues of glufosinate ammonium and its metabolites N-acetyl glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

10d. ***Sugar Beet:*** The petitioner has requested a sugar beet molasses tolerance of 5.0 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

10e. Sugar beets treated three times with Liberty™ Herbicide (2-leaf stage, 6-leaf stage and 8-leaf stage) at 2.5 - 2.7 lbs ai/acre/application (total applied 7.9 lbs ai/acre; 8.3x the maximum proposed seasonal application rate) were harvested 136 days after the final treatment and processed into pulp, molasses and sugar. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate did not concentrate in pulp or sugar but did concentrate 6.8x in molasses. Unprocessed sugar beet samples were stored for 5 months prior to analysis (adequate storage stability study covers this interval). Processed samples were stored for 3 months prior to analysis. No storage stability data for sugar beet pulp, molasses or sugar have been submitted.

The highest average field trial (HAFT) for sugar beet roots was 0.719 ppm (Fayette, OH; MRID 44358603). The maximum combined glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate residue expected in sugar beet molasses, based on the HAFT and the 6.8x concentration factor, is 5.0 ppm.

10f. HED will not be opposed to conditional registration of glufosinate ammonium on transgenic sugar beets. Unconditional registration may be granted upon validation of the three month storage interval for the processed commodities (sugar, pulp and molasses). Pending submission and evaluation of this data, HED concludes that the petitioners proposed sugar beet molasses tolerance of 5.0 ppm is appropriate.

10g. ***Potato:*** The petitioner has requested a potato flake tolerance of 1.3 ppm and a processed potato tolerance of 1.0 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

10h. The submitted potato processing study is adequate (MRID 44358612). Potatoes harvested 9 days after a single treatment with glufosinate ammonium at 2.0 lbs ai/acre (5.3x the maximum proposed single and seasonal application rate) were processed into chips, flakes and peel. The combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid did not concentrate in the peel but did concentrate 2.3x in potato chips and 3.0x in potato flakes.

The HAFT for potatoes was 0.662 ppm (Lee, FL; MRID 44583901). The maximum combined glufosinate ammonium and 3-methylphosphinico propionic acid residue expected in potato flakes, based on the HAFT and the 3.0x concentration factor, is 2.0 ppm. The maximum combined glufosinate ammonium and 3-methylphosphinico propionic acid residue expected in potato chips, based on the HAFT and the 2.3x concentration factor, is 1.6 ppm.

10i. HED concludes that the appropriate tolerance in/on potato chips and potato granuales/flakes, as a result of the application of glufosinate ammonium to potatoes as defined in this petition, is 1.6 ppm and 2.0 ppm, respectively. The petitioner must submit a revised Section F proposing a potato chip tolerance of 1.6 ppm and a potato granule/flake tolerance of 2.0 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

OPPTS GLN 860.1850 & 860.1900: Confined/Field Accumulation in Rotational Crops

11. The submitted label indicates a 120 day plant back interval for wheat only. The label should be amended to indicate a 120-day plant back interval for all crops except wheat where a 70-day plant back interval is appropriate.

Other Considerations

13. Codex currently has MRLs for the combined residues of glufosinate ammonium and and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents in/on potatoes and sugar beets at 0.5 and 0.05 ppm, respectively (no MRLs established for canola). Canada currently has MRLs for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid in/on potatoes and canola at 0.4 ppm and 3.0 ppm, respectively (no MRLs established for sugar beets). No glufosinate ammonium MRLs have been established in/on potatoes, sugar beets or canola in Mexico.

    The Canadian MRL for canola seed is greater than two times the appropriate US tolerance for canola seed; therefore, harmonization is not possible. Since the appropriate US tolerance for sugar beets and potatoes are greater than the Canadian and Codex MRLs, harmonization is not possible.

RECOMMENDATIONS

HED will not be opposed to conditional registration of glufosinate ammonium on transgenic sugar beets. Unconditional registration may be granted upon submission and evaluation of the information specified in conclusions 2a, 2c, 5d, 9f and 10f. HED concludes that the following tolerances for the combined residues of glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents, as a result of the application of glufosinate ammonium to transgenic sugar beets as defined in the petition, are appropriate:

Sugar Beet, Top	1.5 ppm
Sugar Beet, Root	0.9 ppm
Sugar Beet, Molasses	5.0 ppm

HED will not be opposed to conditional registration of glufosinate ammonium on transgenic canola. Unconditional registration may be granted upon submission and evaluation of the information specified in conclusions 2b, 2c, 5d and 10c. HED concludes that the following tolerances for the combined residues of glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents, as a result of the application of glufosinate ammonium to transgenic canola as defined in this petition, are appropriate:

Canola Seed	0.4 ppm
Canola, Meal	1.1 ppm

HED will not be opposed to conditional registration of glufosinate ammonium on potatoes. Unconditional registration may be granted upon submission and evaluation of the information specified in conclusions 2c, 5d, 9i and 10i. HED concludes that the following tolerances for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents, as a result of the application of glufosinate ammonium to potatoes as defined in this petition, are appropriate:

Potato	0.8 ppm
Potato, chip	1.6 ppm
Potato, granules/flakes	2.0 ppm

A human-health risk assessment will be prepared as a separate document.

DETAILED CONSIDERATIONS

OPPTS GLN 830 Series: Product Properties

Product chemistry data for glufosinate ammonium has been submitted, reviewed and found acceptable. No additional product chemistry data is necessary for this petition (PP#8F3607, J. Garbus, 14-Oct-1988 and 8-Aug-1990).

The active ingredient in the technical and formulated products is identified as glufosinate ammonium and concentrations are reported in terms of the racemic mixture.

OPPTS GLN 860.1200: Directions for Use

The petitioner is requesting registration of Liberty™ Herbicide (18.19% glufosinate ammonium; 1.67 lbs ai/US gallon; EPA Reg. No. 45639-199) for use on the transgenic varieties of sugar beet and canola and Rely® Herbicide (11.33% glufosinate ammonium; 1.00 lbs ai/US gallon; EPA Reg. No. 45639-187) for use in potato vine dessication. Both products are water-soluble and applied as a foliar spray. The Liberty™ label indicates that a 120 day interval from the last application is required prior to planting wheat and grazing treated crop or cut for hay is prohibited.

Sugar Beets: Applications of Liberty™ Herbicide may be made from the cotyledon stage up to the 10 leaf stage. Maximum recommended single application rate is 0.48 lbs ai/acre. A maximum of 0.95 lbs ai/acre can be applied per season. Application can be made with ground (controlled droplet application equipment or air assisted spray equipment; minimum of 10 gallons of water/acre) or aerial (minimum of 5 gallons of water/acre) equipment. The label specifies a 60 day pre-harvest interval (PHI).

Canola: Applications of Liberty™ Herbicide may be made from the cotyledon stage up to the early bolting stage (at this stage the plant has at least 6 leaves). A maximum of two applications per season is allowed with the total seasonal rate not to exceed 0.77 lbs ai/acre. Application can be made with ground (controlled droplet application equipment or air assisted spray equipment; minimum of 10 gallons of water/acre) or aerial (minimum of 5 gallons of water/acre) equipment. The label specifies a 65 day PHI.

Potato: Application of Rely® Herbicide is recommended at the beginning of natural vine senescence. The product is to be applied at a rate of 0.375 lbs ai/acre in 20-100 gallons of water per acre with ground equipment or in 5-10 gallons of water per acre with aerial equipment. The label specifies a 9 day PHI. Potatoes grown for seed stock are not to be treated.

Conclusion: The sugar beet portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that the maximum single application rate is 42 fluid ounces/acre (0.48 lbs ai/acre).

The maximum seasonal application rate for canola is listed as 0.77 lbs ai/acre in the application timing section and 0.73 lbs ai/acre in the special notes section (0.77 lbs ai/acre will be assumed to be correct). The petitioner indicated that only the spring variety of canola has been genetically modified for tolerance to glufosinate ammonium. In Region 2, canola is only planted in the winter months (winter variety of canola) due to the unfavorable climate for canola in the summer. Therefore, the petitioner is not requesting registration of transgenic canola in Region 2. The canola portion of the Liberty™ Herbicide label should be amended to indicate in the "Special Notes" section that use of this product on transgenic canola in Region 2 is prohibited.

Both the Rely® Herbicide and Liberty™ Herbicide labels should be amended to indicate a 120 day plant back interval for all crops except wheat where a 70 day plant back interval is appropriate.

OPPTS GLN 860.1300: Nature of the Residue - Plants

SUGAR BEETS

MRID 44358601: C^{14}-Labeled Glufosinate-ammonium (Hoe 039866) Metabolism in Genetically Modified Sugar Beets (Beta *vulgaris* ssp *vulgaris* var *altissima*) After Two Applications of C^{14}-Glufosinate-Ammonium at a Rate of 600 g ai/ha Each: The in-life and analytical phases of the study were conducted by Hoechst Schering AgrEvo GmbH (Frankfurt, Germany). 3,4[C^{14}]Glufosinate-ammonium (specific activity 52,413 dpm/µg, radiochemical purity 98.3%) was applied to transgenic sugar beets as a foliar spray 35 and 57 days after planting at 600 g ai/ha (0.54 lbs ai/acre, 1.1x proposed maximum single application rate); the total application rate was 1.2 kg ai/ha (1.07 lbs ai/acre; 1.1x the proposed maximum seasonal rate). Samples were collected 0, 8, and 15 days following the first application, 0 and 21 days following the second application, and at maturity (146 days following the second application). The plants were divided into leaves (tops) and beets (when formed). Leaves were rinsed with water and the water rinse collected

Extraction and Characterization of Residues: The root and rinsed leaves were homogenized. Radioactivity in rinses and homogenate were determined by LSC or combustion/LSC (limit of quantitation (LOQ) = 0.0011 ppm). The petitioner also determined TRR by summing the radioactivity in extracts and solids following extraction. Both TRR values are summarized in Table1. The petitioner used the summed TRR values for all subsequent calculations.

Table 1: TRR in transgenic sugar beet

	TRR, ppm [^{14}C]glufosinate-ammonium equivalents					
	0 day PHI [1]		21 day PHI		146 day PHI	
Commodity	Combustion [2]	Extraction [3]	Combustion [2]	Extraction [3]	Combustion [2]	Extraction [3]
Rinse	11.95	11.95	1.68	1.68	0.06	0.06
Tops	8.30	8.14	9.62	10.58	2.02	1.99
Total (tops)	20.25	20.08	11.30	12.26	2.08	2.05
Roots	1.97	2.01	6.47	6.75	0.84	0.93

[1] PHI = preharvest interval; days from second treatment
[2] TRR determined by combustion of entire sample
[3] TRR determined by summing radioactivity in extracts and solids remaining following extraction

The 0, 21 and 146 day (days after second treatment) homogenized sugar beet top and root samples were extracted with a water/methanol solution (90/10 v/v) and centrifuged. The supernatant was isolated and the extraction was repeated until greater than 95% of TRR had been extracted, or the extract contained less than 2% of the TRR. Extracts were concentrated and reserved for HPLC and TLC analysis.

HPLC analysis were conducted using a Spherisorb SAX (strong basic anion exchange) column and an isocratic mobile phase of phosphoric acid/potassium dihydrogen phosphate (5 mM, pH = 2) and methanol (System 1 - 90:10 (v:v); System 2 - 30:70 (v:v)). The petitioner claimed that the two different solvent systems separated the analytes by two different mechanisms: System 1 by ion-exchange chromatography and System 2 by adsorption chromatography. Radioactivity was detected and quantified using a radioactivity monitor. The petitioner attempted to conduct TLC analysis to confirm identifications of metabolites. However, matrix effects prevented good separation of metabolites.

Therefore, identification of metabolites was confirmed by identification and quantification in HPLC systems 1 and 2. The distribution of radioactive residues in the water rinse, rinsed leaves and roots are summarized in Table 2. A summary of the characterized and identified ^{14}C-residues in sugar beet commodities are presented in Table 3 (see attachment 1 for structures of identified compounds).

The petitioner also extracted and analyzed crop samples collected after the first treatment but before the second treatment. The rinsates of plants collected 3 hours, 8 days and 15 days following the first treatment contained glufosinate ammonium at 40.5%, 18.8% and 13.8% TRR in tops, respectively. Isomeric separation (using HPLC with a Crompak CR column) demonstrated equal proportions of D and L isomers in the rinsates from all PHIs. In the homogenate extract of tops collected 3 hours after the first treatment, 45.1% of TRR was parent and 9.0% TRR was N-acetyl glufosinate. In the homogenate extract of tops collected 15 days after the first treatment, 29.3% of TRR was parent and 48.6% of TRR was N-acetyl glufosinate. Isomeric separation of the parent peak from the homogenate extracts (tops) demonstrated equal proportions of the D and L isomers on day 0. However, by 15 days following treatment, the D isomer of the parent accounted for 25.2% of TRR and the L-isomer accounted for 3.3% of TRR, indicating that acetylation of glufosinate-ammonium in the transgenic plants occurs with the L isomer only.

Storage Stability: Samples of sugar beet commodities were stored frozen prior to analysis. The petitioner stated that samples were extracted and analyzed within 30 days of harvest except for 0-day PHI root samples which were stored for over 30 days prior to analysis (exact storage interval not provided). Leave and root samples (PHI = 146 days) were stored frozen for 3 months and extracted and analyzed a second time. The initial extract and the extract from the samples stored three months were qualitatively and quantitatively similar indicating that glufosinate ammonium residues in/on sugar beet roots and leaves are stable for 3 months when stored frozen.

Table 2: Distribution and characterization radioactive residues in transgenic sugar beet

Fraction	% TRR	ppm	Characterization/Identification		
0 day PHI Tops (TRR = 20.08 ppm)					
Rinsate	59.50	11.95	Glufosinate-ammonium	59.4% TRR	11.92 ppm
Water:methanol	39.47	7.93	Glufosinate-ammonium MP-propionic acid N-acetyl-glufosinate	25.2% TRR 0.4% TRR 13.4% TRR	5.05 ppm 0.07 ppm 2.68 ppm
Nonextractable	1.03	0.21	Not further analyzed (N/A).		
0 day PHI Roots (TRR = 2.01 ppm)					
Water:methanol	97.39	1.95	Glufosinate-ammonium MP-propionic acid N-acetyl-glufosinate	30.9% TRR 2.2% TRR 64.3% TRR	0.62 ppm 0.04 ppm 1.28 ppm
Nonextractable	2.61	0.05	N/A.		
21 day PHI Tops (TRR = 12.26 ppm)					
Rinsate	13.68	1.68	Glufosinate-ammonium	13.7% TRR	1.68 ppm
Water:methanol	85.03	10.42	Glufosinate-ammonium MP-propionic acid N-acetyl-glufosinate	28.1% TRR 1.1% TRR 55.2% TRR	3.44 ppm 0.13 ppm 6.77 ppm
Nonextractable	1.29	0.16	N/A.		

Fraction	% TRR	ppm	Characterization/Identification		
21 day PHI Roots (TRR = 6.75 ppm)					
Water:methanol	96.39	6.50	Glufosinate-ammonium	30.6% TRR	2.07 ppm
			MP-propionic acid	2.0% TRR	0.14 ppm
			N-acetyl-glufosinate	63.3% TRR	4.27 ppm
Nonextractable	3.61	0.24	N/A.		
146 day PHI Tops (TRR = 2.05 ppm)					
Rinsate	3.01	0.06	Glufosinate-ammonium	2.3% TRR	0.05 ppm
			MP-propionic acid	0.3% TRR	0.006 ppm
			N-acetyl-glufosinate	0.2% TRR	0.005 ppm
			2-methylphosphinico-acetic acid	0.07% TRR	0.001 ppm
			Plus 1 unknown peak	0.09% TRR	0.002 ppm
Water:methanol	94.48	1.94	Glufosinate-ammonium	24.0% TRR	0.49 ppm
			MP-propionic acid	2.7% TRR	0.055 ppm
			N-acetyl-glufosinate	66.9% TRR	1.37 ppm
Nonextractable	2.51	0.05	N/A.		
146 day PHI Roots (TRR = 0.93 ppm)					
Water:methanol	96.25	0.89	Glufosinate-ammonium	19.1% TRR	0.18 ppm
			MP-propionic acid	6.0% TRR	0.055 ppm
			N-acetyl-glufosinate	67.9% TRR	0.63 ppm
			Plus 1 unknown peak	3.1% TRR	0.03 ppm
Nonextractable	3.75	0.03	N/A.		

Table 3: Summary of radioactive residues characterized/identified in transgenic sugar beet

Fraction	0 Day PHI Tops (TRR = 20.08 ppm)		21 Day PHI Tops (TRR = 12.26 ppm)		146 Day PHI Tops (TRR = 2.05 ppm)		0 Day PHI Roots (TRR = 2.01 ppm)		21 Day PHI Roots (TRR = 6.75 ppm)		146 Day PHI Roots (TRR = 0.93 ppm)	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
Identified [1]												
Glufosinate-ammonium	84.6	16.97	41.8	5.12	26.3	0.54	30.9	0.62	30.6	2.07	19.1	0.18
MP-propionic acid	0.4	0.07	1.1	0.13	3.0	0.061	2.2	0.04	2.0	0.14	6.0	0.055
N-acetyl-glufosinate	13.4	2.68	55.2	6.77	67.1	1.38	64.3	1.28	63.3	4.27	67.9	0.63
2-methylphosphinico-acetic acid	--	--	--	--	0.07	0.001	--	--	--	--	--	--
Total identified	**98.4**	**19.72**	**98.1**	**12.02**	**96.5**	**1.98**	**97.4**	**1.94**	**95.9**	**6.48**	**93.0**	**0.87**
Unknown	--	--	--	--	0.09	0.002	--	--	--	--	3.1	0.03
Nonextractable	1.03	0.21	1.29	0.16	2.51	0.05	2.61	0.05	3.61	0.24	3.75	0.03

[1] See Attachment 1 for chemical structures of identified metabolites.

Sugar Beet Metabolism Summary: The qualitative nature of glufosinate ammonium residues in transgenic sugar beets is adequately understood. Total radioactive residues (TRR) were 2.05 ppm in tops and 0.93 ppm in roots harvested 146 days following the last of 2 applications of [C^{14}]glufosinate-ammonium at 0.54 lbs ai/acre (total application rate 1.07 lbs ai/acre, 1.1x the maximum proposed single and seasonal application rates). Samples of sugar beet commodities were also collected at shorter preharvest intervals (PHIs); TRR were 20.08 ppm in tops and 2.01 ppm in roots collected 1 hour after the second application and were 12.26 ppm in tops and 6.75 ppm in roots collected 21 days after the second application.

In sugar beet tops and roots (all PHIs), 93-98% of the TRR was identified. The N-acetyl glufosinate metabolite was the major residue in all sugar beet top and root samples (55.2-67.9% TRR), except 0-day PHI tops where glufosinate ammonium accounted for 84.6% of the TRR (N-acetyl glufosinate accounted for 13.4% of the TRR). Glufosinate-ammonium accounted for 19.1-41.8% of the TRR in all other sugar beet top and root samples. 3-Methylphosphinico propionic acid was identified at low levels in all sugar beet samples (0.4-6.0% TRR). One additional metabolite, 2-methylphosphinico acetic acid, was identified in 146 day PHI tops at 0.07% TRR.

The current tolerance expression for commodities derived from transgenic crops includes the major residues identified in the transgenic sugar beet metabolism study and is adequate for commodities derived from transgenic sugar beets. The residues of concern in/on transgenic sugar beets are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate.

CANOLA

MRID 443586-06 & -07: (Carbon-14)-Glufosinate-Ammonium: Nature of Seed Residue in Transgenic Canola (Rapeseed): The in-life phase of the study was conducted by Research for Hire (Porterville, CA) and the analytical phase of the study was conducted by Hazleton Wisconsin, Inc. (Madison, WI). 3,4[C^{14}]Glufosinate-ammonium (specific activity 20.62 mCi/g, radiochemical purity 98%) was applied to canola plants at the 3-5 leaf stage as a foliar spray at 0.75 kg ai/ha (0.67 lbs ai/acre; 0.9x the proposed maximum seasonal rate). Samples were collected 1 hour postreatment, 21 days posttreatment and at maturity (120 days posttreatment). The 1 hour post application sample was collected as a whole sample. The 21 day sample was separated into top growth and roots. The 120 day sample was separated into roots, top growth and seed pods (seeds and hulls). Plants were separated into top growth (foliage) and roots by cutting approximately 0.5 - 1 inch above the soil. The roots (21 day and 120 day samples) and foliage (120 day samples) were separately rinsed with water (twice). Seed pods were rinsed with water (twice) and separated by hand into seeds and hulls. Samples, including rinsates, were stored frozen (-20 C) until analysis.

Extraction and Characterization of Residues: The rinsed hull, seed, stalk and root samples were homogenized. Radioactivity in the rinses and homogenate were quantified by LSC or combustion/LSC (limit of detection (LOD) = 0.005 ppm). Radioactivity in rinsate samples were not expressed in terms of radioactivity in the crop commodity. The radioactivity in the hull and foliage rinsates from the 120 day treated samples were essentially the same as that attained for control samples. The TRR in canola commodities are presented in Table 4.

Table 4: TRR in transgenic canola

Commodity	TRR, ppm [^{14}C]glufosinate-ammonium equivalents		
	1 hour PHI	21 day PHI	120 day PHI
Whole plant	144.578	--	--
Foliage (top growth)	--	3.207, 5.343	0.021, 0.024, 0.058, 0.064
Roots	--	3.807, 5.192	0.134, 0.150, 0.187, 0.220
Hulls	--	--	0.076, 0.106, 0.125, 0.263
Seed	--	--	0.045, 0.054, 0.056, 0.109

Canola seed and hulls samples were subjected to sequential extraction with hexane, acetone and water/methanol (90:10, v/v). Non-extractable residues from canola seed were subjected to further extraction procedures to characterize nonextractable residues. Residues were first subjected to a second extraction with water:methanol (90:10, v:v). Water-soluble polysaccharides and proteins were extracted using 0.05 M dipotassium hydrogen phosphate buffer (4 hours at room temperature). Lipids were extracted using methanol:chloroform (2:1, v:v) and acetone. The remaining solids were acid hydrolyzed using 1 M hydrochloric acid (at 55 C for 90 minutes) and base hydrolyzed using 0.5 M sodium hydroxide (at 55 C for 45 minutes).

The homogenate from the 1 hour posttreatment sample (whole plant; root and foliage) as well as canola foliage homogenate collected 21 days posttreatment were extracted with water and centrifuged; the extraction was repeated three more times and extracts were combined for HPLC analysis.

HPLC analysis was conducted using either a Spherisorb SAX column and a gradient mobile phase of potassium dihydrogen phosphate buffer and methanol (System 1) or LC-8 and RX-C8 columns (in series) and an isocratic mobile phase of potassium dihydrogen phosphate buffer (System 2). Radioactivity was detected and quantified using fraction collection followed by LSC analysis. Seed and hull samples were analyzed using HPLC systems 1 and 2 (whole plant and foliage samples analyzed by system 1 only). Different levels of the parent and the 3-methylphosphinico propionic acid metabolite in extracts were observed depending on which system was used. No explanation was provided for this difference.

TLC analysis was conducted to confirm identification of metabolites. Radioactivity on TLC plates was detected and quantified using a signal analyzer and a digital autoradiography program. For seed and hull analysis, low levels of radioactivity and matrix effects prevented good separation of metabolites. Although there were some matrix effects, the presence of glufosinate-ammonium and N-acetyl-glufosinate in 1-hour PHI whole plant (root and foliage) and 21-day PHI foliage extracts were confirmed by TLC. A summary of the distribution and identification of metabolites in glufosinate tolerant canola is presented in Table 5 (see Attachment 1 for structures of identified metabolites).

Storage Stability: Samples were stored in a freezer within 24 hours of collection and remained frozen until analysis. Dates of extraction and analysis were not provided. Based on sample collection date and study completion date, samples of canola seed and hulls (MRID 44358606) were extracted and analyzed within 5 months of collection, and samples of whole plant and canola foliage (MRID 44358607) were extracted and analyzed within 19 months of collection.

A storage stability study performed on transgenic soybean demonstrated that glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate are stable for 12 months in soybean seed, forage and hay and for 3 months in soybean oil and meal (D211531 D219069, M. Rodriguez, 7-Mar-1996). This information is sufficient to support the storage conditions and intervals for canola seed and hull samples. The storage interval for whole canola plant and forage has not been validated.

Table 5: Distribution and characterization radioactive residues in transgenic canola

Fraction	% TRR	ppm	Characterization/Identification
1 Hour PHI Plant (TRR = 144.58 ppm)			
Water	98.9	142.97	HPLC analysis (System 1) resolved: Glufosinate-ammonium 72.9% TRR 105.4 ppm N-acetyl-glufosinate 18.2% TRR 26.3 ppm **Total identified 91.1% TRR 131.7 ppm**
Nonextractable	0.24	0.34	Not further analyzed (N/A).
21 Day PHI Foliage (TRR = 5.343 ppm)			
Water	99.2	5.30	HPLC analysis (System 1) resolved: Glufosinate-ammonium 20.7% TRR 1.11 ppm MP-propionic acid 6.7% TRR 0.358 ppm N-acetyl-glufosinate 60.2% TRR 3.22 ppm **Total identified 87.6% TRR 4.69 ppm**
Nonextractable	2.24	0.12	N/A.
120 Day PHI Seeds (TRR = 0.109 ppm)			
Hexane	4.5	0.005	N/A.
Acetone	6.6	0.007	N/A.
Water:methanol	55.7	0.061	HPLC analysis (System 1) resolved: Glufosinate-ammonium 10.8% TRR 0.012 ppm MP-propionic acid 26.8% TRR 0.029 ppm N-acetyl-glufosinate 8.6% TRR 0.009 ppm **Total identified 54.8% TRR 0.060 ppm** HPLC analysis (System 2) resolved: Glufosinate-ammonium 30.1% TRR 0.033 ppm MP-propionic acid 6.5% TRR 0.007 ppm **Total identified 36.7% TRR 0.040 ppm**
Nonextractable	37.8	0.041	Subjected to sequential extraction/hydrolysis procedures using water:methanol, phosphate buffer, methanol:chloroform, acetone, mild acid, and mild base.
Water:methanol	3.8	0.004	N/A.
Phosphate	12.4	0.014	N/A.
Methanol:chloroform	1.3	0.001	N/A.
Acetone	3.4	0.004	N/A.
Acid hydrolysate	4.9	0.005	N/A.
Base hydrolysate	4.8	0.005	N/A.

Fraction	% TRR	ppm	Characterization/Identification
Nonextractable	6.9	0.008	N/A.
120 Day PHI Hulls (TRR = 0.263 ppm)			
Hexane	ND	ND	N/A.
Acetone	ND	ND	N/A.
Water:methanol	77.1	0.203	HPLC analysis (System 1) resolved: Glufosinate-ammonium 5.0% TRR 0.013 ppm MP-propionic acid 37.4% TRR 0.098 ppm N-acetyl-glufosinate 7.3% TRR 0.019 ppm **Total identified 49.7% TRR 0.131 ppm** HPLC analysis (System 2) resolved: MP-propionic acid 44.8% TRR 0.118 ppm N-acetyl-glufosinate 13.9% TRR 0.037 ppm **Total identified 58.7% TRR 0.154 ppm** two unknowns 23.2% TRR 0.061 ppm 2.3% TRR 0.006 ppm
Nonextractable	37.4	0.098	N/A.

ND = not detected

Canola Metabolism Study Summary: Total radioactive residues (TRR) were 0.021-0.064 ppm in foliage, 0.134-0.220 ppm in roots, 0.076-0.263 ppm in hulls, and 0.045-0.109 ppm in seed harvested 120 days (at maturity) following a single application of [^{14}C]glufosinate-ammonium at 0.67 lbs ai/acre (0.9x the maximum proposed seasonal rate). Samples of canola commodities were also collected at shorter PHIs; TRR were 144.578 ppm in the entire plant collected at 1-hour PHI, and were 3.207 and 5.343 ppm in foliage, and 3.807 and 5.192 ppm in roots collected at 21-day PHI.

In the whole plant harvested 1 hour posttreatment, the parent accounted for the majority of the radioactivity (72.9% TRR, 105.4 ppm); N-acetyl-glufosinate was identified at 18.2% of the TRR (26.3 ppm). In foliage harvested 21 days posttreatment, the major residue was N-acetyl-glufosinate (60.2% TRR, 3.22 ppm); the parent was present at 20.7% of the TRR (1.11 ppm) and a small amount of 3-methylphosphinico propionic acid was identified (6.7% TRR, 0.358 ppm).

In mature canola seed and hulls (0.109 ppm and 0.263 ppm, respectively), 37-58% of the TRR was identified (the remainder of the extracted radioactivity was described as unknown metabolites equivalent to the LOD). Glufosinate-ammonium and 3-methylphosphinico propionic acid were the major residues identified, accounting for 5.0-44.8% of the TRR (0.007-0.118 ppm). The N-acetyl-glufosinate metabolite was a minor residue accounting for 1.1-13.9% of the TRR (0.001-0.037 ppm). In canola seed, radioactive residues associated with water-soluble polysaccharides and/or proteins accounted for 12.4% of the TRR (0.014 ppm).

The submitted study is marginally adequate to describe the nature of the residue in glufosinate tolerant canola. The test substance was applied at less than 1x the maximum proposed seasonal rate which resulted in low levels of radioactivity in canola seed, making identification of residues difficult. The storage interval prior to analysis and extraction of whole plant and canola foliage (19 months) were not within the validated time interval (12 months). Seed and hull samples were analyzed using HPLC

systems 1 and 2 (whole plant and foliage samples analyzed by system 1 only). Different levels of parent, N-acetyl glufosinate and 3-methylphosphinico propionic acid were observed depending on which system was used. No explanation for this difference was provided. Since adequate metabolism studies on the transgenic varieties of field corn and soybeans have been previously submitted (D211531 and D219069, M. Rodriguez, 7-Mar-1996) and the results from the canola study do not significantly differ from these studies, no additional data pertaining to the metabolism of glufosinate-ammonium in transgenic canola are required. The residues of concern in/on transgenic canola are glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate.

POTATO

Nature of the Residue Potato: The nature of the residue is considered to be understood in genetically unaltered lettuce, soybeans, corn, apples and wheat. After application of ^{14}C glufosinate ammonium to the nutrient medium (water or soil) in which these crops were grown, only one labeled metabolite could be identified, 3-methylphosphinico propionic acid (parent was not found). HED concluded that the residues to be regulated in commodities derived from genetically unaltered lettuce, soybeans, corn, apples and wheat are glufosinate ammonium and 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990).

A metabolism study has not been performed on a root vegetable (potato). Since the metabolism of glufosinate ammonium is consistent in four diverse crops groups (lettuce [leafy vegetable], soybeans [legume vegetable], wheat [cereal grain] and apple [fruit]) the nature of glufosinate ammonium residues in potatoes will be considered to be understood. The residues of concern in/on potatoes are glufosinate ammonium and 3-methylphosphinico propionic acid.

OPPTS GLN 860.1300: Nature of the Residue - Animals

The nature of glufosinate ammonium residues in lactating goats and hens is considered to be understood . It was shown that the glufosinate ammonium and its metabolite (3-methylphosphinico propionic acid) are largely excreted and do not accumulate too any great degree in animal tissues. The only identifiable compounds in feces, urine, milk, eggs and tissues were the parent and 3-methylphosphinico propionic acid. HED concluded that the residues of concern in commodities derived from ruminants and poultry are glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990).

Transgenic field corn, soybeans, canola and sugar beets contain a second metabolite, N-acetyl glufosinate, which may lead to secondary residues of this compound in animal commodities. Feeding studies conducted on dairy cows and laying hens were submitted and reviewed as part of glufosinate ammonium registration on transgenic field corn and transgenic soybeans. In these studies, dairy cows and hens were feed a diet consisting of glufosinate ammonium and N-acetyl glufosinate. It was determined, that the tolerance expression for poultry (new tolerance as a result of registration on transgenic soybeans and transgenic field corn) should include glufosinate ammonium and 3-methylphosphinico propionic acid (N-acetyl glufosinate should not be included; D232571, M. Rodriguez). Additionally, it was determined that the currently established egg, milk, and fat, meat, and meat byproducts tolerances on cattle, goats, hogs, horses, poultry, and sheep were adequate (D211531 and D219069, M. Rodriguez, 7-Mar-1996).

OPPTS GLN 860.1340: Residue Analytical Method

Analytical methodology is available in PAM II for determination of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in genetically unaltered apples, bananas, grapes and tree nuts (HRAV-5A) and in milk, eggs and the tissues of ruminants and poultry (HRAV-12, also called BK/01/95). Method HRAV-5A employs extraction of glufosinate ammonia and its metabolite 3-methylphosphinico propionic acid from a 25 gram homogenized sample with water. The aqueous extract is filtered and subjected to anion-exchange chromatography for removal of interfering compounds. The residues are eluted from the resin with formic acid and derivatized by refluxing with trimethylorthoacetate. The derivatized residues are cleaned up on a silica gel column and quantified by GC/FPD. All compounds are quantified in terms of glufosinate free acid equivalents. Method HRAV-12 (used to determine residue levels in animal matrices) is similar to the plant method except for an addition step. Water extracts of tissues are diluted with acetone to precipitate protein, centrifuged and then subjected to anion ion-exchange chromatography.

In transgenic crops a second metabolite, N-acetyl glufosinate, is present. Since glufosinate ammonium and N-acetyl glufosinate are derivatized to the same compound, HRAV-5A does not distinguish between these two compounds. A second method, AE-24, was developed for individual determination of the three compounds regulated in commodities derived from transgenic crops. Method AE-24 is a modification of the current analytical enforcement method (HRAV-5A) in that following anion exchange, cation exchange is performed. Two fractions are collected from the cation ion exchange column. One fraction contains N-acetyl glufosinate and 3-methylphosphinico propionic acid and the second fraction contains glufosinate ammonium. Each fraction is derivatized by refluxing with trimethylorthoacetate, cleaned up on a silica gel column and quantified by GC/FPD.

Several variations of these two methods were used for quantitation of residues in the submitted field trials; all of which are adequate for data gathering purposes. The petitioner also submitted a brief description of a GC/MS confirmatory technique. Validation data was not conducted for all methods and/or matrices. However, concurrent recovery data demonstrated the adequacy of each method in all necessary matrices.

Table 6: Validation Recoveries

commodity	fortification (ppm)	% recovery[1]		
		HOE 039866 [2]	HOE 099730 [2]	HOE 061517 [2]
canola seed HRAV-24 MRID 44358608	0.05-0.20	80.2-87.6 (3), **84.0**	70.5-88.9 (3), **79.7**	83.5-107 (3), **97.8**
canola seed XAM-24 MRID 44358609	0.05-0.20	83.5-107 (3), **97.8**	80.2-87.6 (3), **84.0**	70.5-88.9 (3), **79.7**
canola soapstock HRAV-24 MRID 44358610	0.05-0.20	89.0, 106; **97.5**	117, 135; **126**	105, 104; **105**
Potato; XAM-24B; MRID44358612				
potato[3]	0.05 - 3.0	79.0 ± 5.3 (6)	*	97.2 ± 5.5 (6)

commodity	fortification (ppm)	% recovery[1]		
		HOE 039866 [2]	HOE 099730 [2]	HOE 061517 [2]
chips	0.05 - 0.50	72.4-98.7 (10); **85.0**	*	86.6-107 (10); **97.9**
flakes	0.05 - 0.50	72.1-99.4 (10); **86.9**	*	77.3-103 (10); **90.9**
wet peel	0.05- 0.50	80.2-113 (10); **96.8**	*	75.3-97.3 (10); **90.8**

[1] range of recoveries; number of samples in parenthesis; average in bold
[2] HOE 039866 = glufosinate ammonium, HOE 099730 = N-acetyl glufosinate, HOE 061517 = 3-methylphosphinico propionic acid
[3] only average and std dev was given for potatoes
* non-transgenic crop; N-acetyl glufosinate is not a metabolite

Table 7: Concurrent Recoveries

commodity	fortification (ppm)	% recovery[1]		
		HOE 039866 [2]	HOE 099730 [2]	HOE 061517 [2]
canola seed HRAV-24 MRID 44358608	0.05-0.20	74.0-87.0 (8), **80.3**	87.4-119 (8), **97.7**	71.6-107 (8), **83.2**
canola seed XAM-24 MRID 44358609	0.05-0.10	69.3-99.0 (6), **85.3**	95.0-120 (6), **108**	91.6-117 (6), **105**
canola; HRAV-24; MRID 44358610				
canola seed	0.05	91.8	109	111
crude oil	0.05	74.1	99.9	96.2
untoasted meal	0.20	99.7	76.2	99.4
toasted meal	1.00	96.6	91.8	106
refined oil	0.05	91.8	120	89.6
refined bleached oil	0.10	92.4	97.0	91.5
refined bleached deodorized oil	0.05	84.1	91.6	70.0
soapstock	0.05	108	127	107
sugar beet; BK/04/95; MRID 44827901 (storage stability study)				
tops	0.25	51.9, 60.8, 68.8, 70.6-80.2 (3), **67.6**	49.6, 70.0-85.8 (5), **72.6**	79.4-118 (10), **98.1**

commodity	fortification (ppm)	% recovery[1]		
		HOE 039866 [2]	HOE 099730 [2]	HOE 061517 [2]
root	0.25	63.8, 79.8-108 (6), **85.2**	82.2-110 (6), **95.9**	73.2-115 (11), **93.7**
sugar beet; BK/04/95; MRID 44358602				
tops and crown	0.05-4.0	73.6-96.3 (9), **83.6**	72.6-117 (18), **86.4**	73.1-114 (9), **83.3**
root	0.05-0.10	87.4-108(5), **98.2**	75.9-112 (10), **91.4**	80.6-96.2 (5), **87.7**
sugar beet; BK/04/95; MRID 44358603				
tops and crown	0.05-1.00	74.2-109 (9), **88.9**	85.6-119 (18), **101**	68.0, 70.1-103 (8), **84.4**
root	0.05-1.00	82.7-117 (10), **96.4**	67.1, 72.8-105 (19), **87.7**	77.4-101 (10), **88.8**
sugar beet; BK/04/95; MRID 44358604				
roots	0.05 - 2.00	87.3; fortified at 0.50	100, 92.5; **96.3** fortified at 0.05 & 2.00	68.0, 87.9, 113; **89.6**
dried pulp	0.05 - 2.00	78.3; fortified at 0.50	104, 107; **106** fortified at 0.05 and 1.00	79.8 - 108 (3); **92.0**
molasses	0.05, 10.0	86.3; fortified at 0.05	88.1, fortified at 10.0	74.0, 106; **90.0**
refined sugar	0.05, 10.0	90.8; fortified at 10.0	94.4, fortified at 0.05	91.3, 111; **101**
potato; XAM-24B; MRID 44358612				
tubers	0.05, 2.50	84.3-89.4 (3); **87.2**	*	86.4-95.9 (3); **90.3**
chips	0.05, 2.00	88.5, 93.5; **91.0**	*	94.0, 102; **98.0**
flakes	0.05, 2.00	89.9, 105; **97.5**	*	85.8, 96.4; **91.1**
wet peel	0.05, 2.50	80.9, 88.9; **84.9**	*	81.9, 92.9; **87.4**
potato; BK/05/95 MRID 44583901	0.05-0.80	92.9-120 (11), **120**	*	88.0-102 (11), **97.0**

[1] range of recoveries; number of samples in parenthesis; average in bold

[2] HOE 039866 = glufosinate ammonium, HOE 099730 = N-acetyl glufosinate, HOE 061517 = 3-methylphosphinico propionic acid

Conclusions: A complete description of the GC/MS confirmatory technique should be submitted by the petitioner.

Two of the methods used for quantification of residues in the field trials, BK/04/95 (used for quantitation of residues in/on transgenic sugar beet commodities) and HRAV-24 (used for quantitation of residues in/on transgenic canola commodities), were submitted to the Analytical Chemistry Branch (ACB) for Petition Method Validation (D254830, T. Bloem, 1-Apr-1999). Method BK/04/95 is similar to the current analytical enforcement method HRAV-5A but with modifications for application to a root crop. Method HRAV-24, which employs the cation exchange fractionation procedure (cation exchange procedure has not undergone Agency validation), was submitted to ACB for validation.

Given that the registrant has provided concurrent fortification data to demonstrate that BK/04/95 and HRAV-24 are adequate for data collection purposes and these methods are a modification of the current tolerance enforcement method, HED concludes that they are suitable enforcement methods to support tolerances associated with a conditional registration on potatoes, transgenic sugar beets and transgenic canola. As a condition of the registration, HED will require a successful petition method validation and the registrant will be required to make any necessary modifications to the method resulting from petition method validation.

OPPTS GLN 860.1360: Multiresidue Method

Glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate were not quantitatively recovered from any of the FDA Multiresidue Testing Protocols. This information has been forwarded to FDA (PP#8F3607, J. Garbus, 14-Aug-1988; PP#5F4578, M. Rodriguez, 10-Oct-1995).

OPPTS GLN 860.1380: Storage Stability Data

The petitioner submitted a storage stability study investigating the recovery of fortified residues of glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate in/on transgenic sugar beet tops and roots (MRID 44827901). The samples were fortified with 0.25 ppm of each compound and frozen until analysis. Stored samples and freshly fortified samples were analyzed using method BK/04/95. Results from the sugar beet storage stability study are presented in Table 8.

Table 8: Storage Stability in Transgenic Sugar Beet Tops and Roots

analyte [2]	fortification (ppm)	storage period (months)	freshly fortified % recovery [1]	apparent recovery in stored samples	corrected % recovery in stored samples
tops					
HOE 039866	0.25	3	60.8	75.6, 59.6	124, 98.0
		6	51.9	68.3, 71.5	132, 138
		12	68.8	64.8, 67.4	94.2, 98.0
		24	80.2	63.6, 64.2	79.3, 80.0

analyte [2]	fortification (ppm)	storage period (months)	freshly fortified % recovery [1]	apparent recovery in stored samples	corrected % recovery in stored samples
HOE 099730	0.25	3	85.8	76.0, 78.8	88.6, 91.8
		6	49.6	56.8, 59.8	115, 121
		12	70.0	80.7, 81.3	115, 116
		24	80.2	67.2, 76.8	83.8, 95.8
HOE 061517	0.25	3	94.8, 99.8	95.1, 87.8	97.7, 90.2
		6	96.6, 105	100, 102	99.2, 101
		12	96.9, 93.9	85.8, 97.5	89.9, 102
		24	118, 116	108, 108	92.3, 92.3
roots					
HOE 039866	0.25	3	79.8, 94.5	81.1, 77.2	93.1, 88.6
		6	86.2	81.2, 88.4	94.2, 103
		12	108	104, 96.0	96.3, 88.9
		24	63.8	73.5, 85.3	115, 135
HOE 099730	0.25	3	87.0	81.7, 71.4	93.9, 82.1
		6	100	106, 105	106, 105
		12	98.5	103, 98.3	105, 99.8
		24	82.2	82.7, 87.2	101, 106
HOE 061517	0.25	3	97.4, 102, 91.6	91.9, 95.2	94.7, 98.1
		6	88.4, 100	107, 117	114, 124
		12	96.6, 85.6	107, 91.0	117, 99.9
		24	106, 115	111, 124	100,112

[1] average of freshly fortified samples used for calculation of % corrected recoveries

[2] HOE 039866 = glufosinate ammonium, HOE 099730 = N-acetyl glufosinate, HOE 061517 = 3-methylphosphinico propionic acid

Conclusions: The submitted storage stability study indicates that glufosiante ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid are stable in transgenic sugar beet tops and roots for 24 months.

Previously submitted and reviewed storage stability data indicate that glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid are stable for 24 months in apples, corn grain and soybeans

(PP#8F3607, J. Garbus, 8-Aug-1990). Additional storage stability data indicate that glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate are stable for 12 months in transgenic soybean seed, forage and hay; for 3 months in soybean oil and meal; for 6 months in transgenic corn grain, fodder and forage; and for 3 months in eggs, liver, kidney and muscle (D211531 and D219069, M. Rodriguez, 7-Mar-1996).

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

Two dairy cow and two poultry feeding studies have been previously submitted, reviewed and determined to be adequate: (**1**) dairy cows and poultry feed a diet containing a 3:1 mixture of glufosinate ammonium and 3-methylphosphinico propionic acid (PP#8F3607, J. Garbus, 8-Aug-1990) and (**2**) dairy cows and poultry feed a diet containing 15% glufosinate ammonium and 85% N-acetyl glufosinate (D211531 & D211531, M. Rodriguez, 7-Mar-1996). Two feeding studies were performed on dairy cows and poultry due the different residues present in transgenic (principally N-acetyl glufosinate followed by glufosinate ammonium) and non-transgenic crops (principally 3-methylphosphinico propionic acid). Since the majority of the dietary burden to ruminants and poultry originates from transgenic crops, the feeding studies performed with N-acetyl glufosinate and glufosinate ammonium will be considered representative.

Considering all registered and proposed crops the maximum theoretical dietary burden is 14.55 ppm for beef cattle (aspirated grain fractions, corn field forage, cannery waste), 14.22 ppm for dairy cattle (aspirated grain fractions, corn field forage, cannery waste, molasses), 2.62 ppm for poultry (soybean hulls, soybean meal, soybean seed, canola meal) and 8.07 ppm for swine (aspirated grain fractions, canola meal, potato culls). Using these dietary burdens and the feeding studies performed with N-acetyl glufosinate and glufosinate ammonium, no adjustment in ruminant and poultry tolerances are necessary.

Table 9: Commodity Contribution to Aninal Dietary Burden

commodity	tolerance (ppm)	% dry matter	% diet				ppm in feed			
			beef	dairy	poultry	swine	beef	dairy	poultry	swine
previously registered commodities										
almond hulls	0.50	90	10	10	*	*	0.06	0.06	*	*
apple pomace	0.05	40	40	20	*	*	0.05	0.03	*	*
aspirated grain fractions	25.0	85	20	20	*	20	5.88	5.88	*	5.88
corn field grain	0.2	88	80	40	80	80	0.18	0.09	0.18	0.18
corn milled by products	0.2	85	50	25	60	75	0.12	0.06	0.14	0.18
[1]corn forage	4.0	40	40	50	*	*	4.00	5.00	*	*
[1]corn stover	6.0	83	25	15	*	*	1.81	1.08	*	*
[1]cannery waste	4.0	30	35	20	*	*	4.67	2.67	*	*
soybean hulls	5.0	90	20	20	20	*	1.11	1.11	1.11	*
soybean meal	2.0	92	15	15	40	25	0.33	0.33	0.87	0.54
soybean seed	2.0	89	15	15	20	25	0.34	0.34	0.45	0.56
soybean silage	2.0	30	30	30	*	*	2.00	2.00	*	*
commodities which are part of this petition										
sugar beet tops	1.5	23	20	10	*	*	1.30	0.65	*	*
sugar beat pulp	0.9	88	20	20	*	*	0.20	0.20	*	*
molasses	5.0	75	10	10	*	*	0.67	0.67	*	*
canola meal	1.1	88	15	15	15	15	0.19	0.19	0.19	0.19
potato culls	0.8	20	75	40	*	50	3.00	1.60	*	2.00
potato processed waste	0.8	15	75	40	*	*	4.00	2.13	*	*

– feeding restriction on soybean forage and hay therefore not include in calculation of dietary burdens
– *italicized commodities* originate from transgenic crops
[1] field or sweet corn forage and stover

OPPTS GLN 860.1500: Crop Field Trials

CANOLA

MRID 44358608: Determination of HOE 039866 Residues and its Metabolites HOE 061517 and HOE 085355 in Glufosinate Tolerant Canola (Brassica Napus) Generated from 1993 Field Trials: A total of 10 field trials were conducted during 1993 in Saskatchewan (n=3), Manitoba (n=3) and Alberta (n=4). Grain samples were harvested 57-83 days following a single broadcast spray application of glufosinate ammonium at 0.44 - 1.78 lbs ai/acre (0.6x - 2.3x the maximum proposed seasonal application rate). Applications were made at the 3-10 leaf stage in 12 gallons water/acre (timing of application at Westlock, Ab not recorded). A minimum of 500 grams of canola seed was collected after mechanical threshing and cleaning. Samples were frozen and shipped frozen to Xenos Laboratories Inc. (Ottawa, Ontario) where they were ground and kept frozen until residue analysis.

Samples were analyzed for residues of glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate using method HRAV-24 (essentially the same as AE-24, LOQ = 0.05 ppm). Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated canola seed are summarized in Table 10. The petitioner indicated that the field portion of this study **was not** conducted according to GLP standards as specified in 40 CFR 160. Samples were stored for a maximum of 12 months prior to extraction and analysis (adequate transgenic soybean storage stability study covers this interval).

Table 10: Residues in/on Transgenic Canola Seed

location	lbs ai/acre	"x" proposed use rate	leaf stage[1]	PHI (days)	ppm [2]			
					039866	061517	085355	total
Innisfail, Ab	0.67	0.9	3-5	80	<0.05	<0.05	<0.05	<0.15
	1.34	1.8	3-5	80	<0.05	<0.05	<0.05	<0.15
	1.34	1.8	3-5	80	<0.05	<0.05	<0.05	<0.15
Westlock, Ab	0.45	0.6	*	75	<0.05	<0.05	<0.05	<0.15
	0.67	0.9	*	75	<0.05	<0.05	<0.05	<0.15
Fairview, Ab	0.45	0.6	4-5	75	<0.05	<0.05	<0.05	<0.15
	1.34	1.8	4-5	75	<0.05	<0.05	<0.05	<0.15
	1.34	1.8	4-5	75	<0.05	<0.05	<0.05	<0.15
Olds, Ab	0.45	0.6	3-5	83	<0.05	<0.05	<0.05	<0.15
	0.67	0.9	3-5	83	<0.05	<0.05	<0.05	<0.15
Brandon, Mb	0.67	0.9	4-6	69	0.122	<0.05	<0.05	<0.222
	0.67	0.9	4-6	69	0.106	<0.05	<0.05	<0.206
Rosebank, Mb	0.41	0.6	4-5	67	<0.05	<0.05	<0.05	<0.15

location	lbs ai/acre	"x" proposed use rate	leaf stage[1]	PHI (days)	ppm[2]			
					039866	061517	085355	total
	0.62	0.8	4-5	67	<0.05	<0.05	<0.05	<0.15
Souris, Mb	0.41	0.6	4-5	68	<0.05	<0.05	<0.05	<0.15
	0.62	0.8	4-5	68	<0.05	<0.05	<0.05	<0.15
Rosthern, Sk	0.94	1.3	5	66	<0.05	<0.05	0.053	<0.153
	1.82	2.5	5	66	<0.05	<0.05	0.098	<0.198
Lake Lenore, Sk	0.54	0.7	3-4	57	<0.05	<0.05	<0.05	<0.15
	0.84	1.2	3-4	57	<0.05	<0.05	<0.05	<0.15
Outlook, Sk	0.52	0.7	10	69	<0.05	<0.05	<0.05	<0.15
	0.8	1.1	10	69	<0.05	<0.05	<0.05	<0.15

[1] leaf stage at application

[2] concentrations expressed in terms of glufosinate free acid equivalents; HOE prefix eliminated; 039866 = glufosinate ammonium, 085355 = N-acetyl glufosinate, 061517 = 3-methylphosphinico propionic acid

* leaf stage at application not recorded

MRID 44358609: Determination of HOE 039866 Residue and its Metabolites HOE 085355 and HOE 061517 in Glufosinate Tolerant Canola (Brassica Napus) Generated from 1994 Field Trials: A total of 4 field trials were conducted during 1994 in Saskatchewan (n=1), Manitoba (n=2) and Alberta (n=1). Grain samples were harvested 57-77 days following a single broadcast spray application of glufosinate ammonium at 0.36, 0.71 or 1.07 lbs ai/acre (0.5x, 0.9x and 1.4x the maximum proposed seasonal application rate). Applications were made at the 1-3 leaf stage or 4-6 leaf stage in 12 gallons water/acre. A minimum of 500 grams of canola seed was collected after mechanical threshing and cleaning. Samples were frozen immediately and shipped frozen to Xenos Laboratories Inc. (Ottawa, Ontario) where they were ground and kept frozen until residue analysis.

Samples were analyzed for residues of glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate using method XAM-24 (essentially the same as AE-24, LOQ = 0.05 ppm). Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated canola seed are summarized in Table 11. The petitioner indicated that this study was conducted according to GLP standards as specified in 40 CFR 160. Samples were stored for a maximum of 4 months prior to extraction and analysis (adequate transgenic soybean storage stability study covers this interval).

Table 11: Residues in/on Transgenic Canola Seed

location	lbs ai/acre	"x" proposed use rate	leaf stage[1]	PHI (days)	ppm[2]			
					039866	061517	085355	total
Indian Head, Sk	0.36	0.5	2-3	73	<0.05	<0.05	<0.05	<0.15
	0.71	1.0	2-3	73	<0.05	<0.05	<0.05	<0.15

location	lbs ai/acre	"x" proposed use rate	leaf stage[1]	PHI (days)	ppm [2]			
					039866	061517	085355	total
	1.07	1.5	2-3	73	<0.05	<0.05	<0.05	<0.15
	0.36	0.5	5-7	57	<0.05	<0.05	0.169	<0.269
	0.71	1.0	5-7	57	<0.05	<0.05	0.236	**<0.336**
	1.07	1.5	5-7	57	<0.05	<0.05	0.255	<0.355
Minto, Mb	0.36	0.5	2	77	<0.05	<0.05	<0.05	<0.15
	0.71	1.0	2	77	<0.05	<0.05	<0.05	<0.15
	1.07	1.5	2	77	<0.05	<0.05	<0.05	<0.15
	0.36	0.5	5-6	70	<0.05	<0.05	<0.05	<0.15
	0.71	1.0	5-6	70	<0.05	<0.05	<0.05	<0.15
	1.07	1.5	5-6	70	<0.05	<0.05	0.055	<0.155
Vauxhall, Ab	0.36	0.5	2-4	77	<0.05	<0.05	<0.05	<0.15
	0.71	1.0	2-4	77	<0.05	<0.05	<0.05	<0.15
	1.07	1.5	2-4	77	<0.05	<0.05	<0.05	<0.15
	0.36	0.5	4-6	67	<0.05	<0.05	0.081	<0.181
	0.71	1.0	4-6	67	<0.05	<0.05	0.171	<0.271
	1.07	1.5	4-6	67	0.053	<0.05	0.242	<0.345
Portage la Prairie, Mb	0.36	0.5	4-5	65	<0.05	<0.05	<0.05	<0.15
	0.71	1.0	4-5	65	<0.05	<0.05	0.066	<0.166
	1.07	1.5	4-5	65	<0.05	0.056	0.053	<0.159

[1] leaf stage at application

[2] concentrations expressed in terms of glufosinate free acid equivalents; HOE prefix eliminated; 039866 = glufosinate ammonium, 085355 = N-acetyl glufosinate, 061517 = 3-methylphosphinico propionic acid

Summary Canola: The petitioner has requested a canola seed tolerance of 0.4 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate. The petitioner indicated that only the spring variety of canola has been genetically modified for tolerance to glufosinate ammonium. In Region 2, canola is only planted in the winter months (winter variety of canola) due to the unfavorable climate for canola in the summer. Therefore, the petitioner is not requesting registration for application of glufosinate ammonium to transgenic canola in Region 2.

The petitioner submitted two field trial studies conducted in Canada (MRID 443586-08 & -09). The field portion of MRID 443586-08 was not conducted according to GLP standards. The deficiencies which lead to nonconformance were not provided. Information pertaining to the application date,

method, equipment, volume, timing and rate were provided. Therefore, the factors that lead to nonconformance with GLP standards will be considered minor and the study is acceptable. The field trial data conducted as part of MRID 443586-09 is also acceptable.

The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate in/on transgenic canola seed following a single application of glufosinate ammonium at 0.9x or 1.3x the maximum proposed seasonal use rate ranged from <0.15 - <0.336 ppm (treated at 3-7 leaf stage; PHI = 57 - 83 days).

According to Table 5 of OPPTS GLN 860.1500, a total of 8 trials conducted in Regions 2 (n=1, not necessary for this petition), 5 (n=2), 7 (n=2) and 11 (n=3) are suggested. The Canadian field trial data submitted with this petition can be applied to the following regions (HED SOP 98_2); Region 7 (n=2) and Region 14 (n=12; Region 14 is unique to Canada). The issue of how to apply canola field trial data from Region 14 to a US Registration was brought to Chem SAC. B. Schneider gathered information on canola production in the US and Canada and concluded that the majority of US canola is grown in ND, MN, MT, WA and SD. Generally within these states the northern most counties are the highest producing areas of the state. The canola production in Region 11 has decreased and increased in Regions 5 and 7 since the guidelines were written. The SAC agreed on accepting the Canadian canola field trials for glufosinate ammonium due to the similarities between the US canola production areas and Region 14 (Minutes of 17-Jun-1999 ChemSAC meeting). Geographical distribution of the submitted field trials is adequate for establishment of a tolerance in/on canola.

HED concludes that based on the submitted field trial data, the petitioners proposed tolerance of 0.4 ppm is appropriate. The Canadian MRL for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid in/on canola is 3.0 ppm. In light of harmonization with Canada, the appropriate tolerance in/on canola seed for the combined residues of glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate ammonium free acid equivalents, is 3.0 ppm.

SUGAR BEET

MRID 44358602: Magnitude of Glufosinate-Ammonium Residues In or On Trangenic Sugar Beets Resulting From Multiple Applications of Liberty™ Herbicide at Three Rates, USA, 1995: A total of 4 field trials were conducted during 1995 in California (n=1; Region 10), Idaho (n=1; Region 11), North Dakota (n=1; Region 5) and Minnesota (n=1; Region 5). One control and three treated plots were planted at each trial site. The first plot was treated three times at a nominal rate of 0.18 lbs ai/acre/application (0.4x the maximum single application rate), once at the 2-leaf stage, once at the 6-leaf stage and once at the 8-leaf stage (total treatment 0.54 lbs ai/acre; 0.6x the maximum seasonal application rate). The second plot was treated three times at a nominal rate of 0.36 lbs ai/acre/application (0.9x the maximum single application rate), at the same growth stages (total treatment 1.08 lbs ai/acre; 1.1x the maximum seasonal application rate). The third plot was treated two times at a nominal rate of 0.54 lbs ai/acre/application (1.3x the maximum single application rate), once at the 6-leaf stage and once at the 8-leaf stage (total treatment 1.08 lbs ai/acre; 1.1x the maximum seasonal application rate). All applications were made over the top with broadcast spray equipment in 10 gallons of water per acre. After collection, the tops plus the crown tissue were cut from the roots and packaged separately. All samples were frozen within 90 minutes of harvest and shipped frozen to the AgroEvo Research Center for homogenization. The homogenized samples were shipped frozen to Xenos laboratories (Ottawa, Ontario) where they were kept frozen until analysis.

Samples were analyzed for residues of glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate using method BK/04/95 (essentially the same as HRAV-5A, LOQ = 0.05 ppm). This method does not distinguish between glufosinate ammonium and N-acetyl glufosinate. Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated sugar beet tops and roots are summarized in Table 12. The petitioner indicated that this study was conducted according to GLP standards as specified in 40 CFR 160 except for a few minor exceptions. Samples were stored for a maximum of 12 months prior to extraction and analysis (adequate storage stability study cover this interval).

Table 12: Residues in/on Transgenic Sugar Beet Tops and Roots

location	total applied (lbs ai/acre)	PHI[1] (days)	tops[2] (ppm)			roots[2] (ppm)		
			039866/ 099730	061517	total	039866/ 099730	061517	total
Fresno, CA	0.55[3]	10	0.19 0.23	<0.05 <0.05	<0.24 <0.28	–	–	–
		15	0.31 0.29	0.14 0.17	0.45 0.46	–	–	–
		30	0.23 0.28	0.53 0.54	0.76 0.82	–	–	–
		60	0.13 0.12	0.37 0.33	0.50 0.45	–	–	–
		139	<0.05 <0.05 <0.05	0.08 0.06 0.12	<0.13 <0.11 <0.17	<0.05 <0.05	0.14 0.14	<0.19 <0.19
	1.10[4]	10	0.39 0.46	<0.05 <0.05	<0.44 <0.51	–	–	–
		15	1.04 1.11 1.22	0.51 0.37 0.48	1.55 1.48 1.70	–	–	–
		30	0.63 0.76	1.20 1.07	1.83 1.83	–	–	–
		60	0.39 0.32	0.88 0.78	1.27 1.10	–	–	–
		139	<0.05 <0.05	0.21 0.25	<0.26 <0.30	<0.05 <0.05	0.30 0.32	<0.35 <0.37
	1.08[5]	10	3.01 3.55	0.25 0.22	3.26 3.77	–	–	–
		15	2.47 2.75 2.02	0.58 0.44 0.42	3.05 3.19 2.44	–	–	–

location	total applied (lbs ai/acre)	PHI[1] (days)	tops[2] (ppm)			roots[2] (ppm)		
			039866/ 099730	061517	total	039866/ 099730	061517	total
		30	1.15 1.25	1.17 1.40	2.32 2.65	–	–	–
		60	0.48 0.60 0.45	0.82 0.70 0.81	1.30 1.30 1.26	–	–	–
		139	0.05 0.08 <0.05	0.29 0.22 0.21	0.34 0.30 <0.26	<0.05 0.05	0.27 0.31	<0.32 0.36
Jerome, ID	0.56[3]	41	0.08 0.09	<0.05 <0.05	<0.13 <0.14	0.06 <0.05 <0.05	<0.05 <0.05 <0.05	<0.11 <0.10 <0.10
	1.11[4]	41	0.22 0.23	<0.05 <0.05	<0.27 <0.28	0.16 0.15	<0.05 <0.05	<0.21 <0.20
	1.10[5]	41	0.31	0.05	0.36	0.21	0.06	0.27
Cass, ND	0.58[3]	104	0.05 0.09 0.05	<0.05 <0.05 <0.05	<0.10 <0.14 <0.10	0.08 0.06 0.08	<0.05 <0.05 <0.05	<0.13 <0.11 <0.13
	1.17[4]	104	0.11 0.07 0.11	<0.05 <0.05 <0.05	<0.16 <0.12 <0.16	0.14 0.15	<0.05 <0.05	<0.19 <0.20
	1.34[5]	104	0.07 0.08	<0.05 <0.05	<0.12 <0.13	0.15 0.12	<0.05 <0.05	<0.20 <0.17
Polk, MN	0.53[3]	95	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10
	1.10[4]	95	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10	0.09 0.09	<0.05 <0.05	<0.14 <0.14
	1.09[5]	95	0.10 0.09	<0.05 <0.05	<0.15 <0.14	0.12 0.10	<0.05 <0.05	<0.17 <0.15

[1] California samples collected at the following plant stages, 10 day PHI = 12-13 leaf stage, 15 day PHI = 13 leaf stage, 30 day PHI = 16-18 leaf stage, 60 day PHI = vegetative, 139 day PHI = mature; Idaho 41 day PHI = immature; North Dakota 104 day PHI = mature; Minnesota 95 day PHI = mature

[2] concentrations expressed in terms of glufosinate free acid equivalents; HOE prefix eliminated; 039866 = glufosinate ammonium, 099730 = N-acetyl glufosinate, 061517 = 3-methylphosphinico propionic acid

[3] three applications at a nominal rate of 0.18 lbs ai/acre, once at the 2-leaf stage, once at the 6-leaf stage and once at the 8-leaf stage (total treatment 0.54 lbs ai/acre, 0.6x maximum seasonal application rate)

[4] three applications at a nominal rate of 0.36 lbs ai/acre at the same growth stages as "1" (total treatment 1.08 lbs ai/acre, 1.1x maximum seasonal application rate)

[5] two applications at a nominal rate of 0.54 lbs ai/acre, once at the 6-leaf stage and once at the 8-leaf stage (total treatment 1.08 lbs ai/acre, 1.1x maximum seasonal application rate)

MRID 44358603: Magnitude of Glufosinate-Ammonium Residues In or On Trangenic Sugar Beet Raw Agricultural Commodities Resulting From Multiple Applications of Liberty™ Herbicide at Two Rates, USA, 1996: A total of 10 field trials were conducted during 1995 in Michigan (n=1; Region 5), Ohio (n=1; Region 5), North Dakota (n=2; Regions 5 and 7), Nebraska (n=1; Region 7), Colorado (n=2; Regions 8 and 9), California (n=1; Region 10) and Idaho (n=2; both in Region 11). One control and two treated plots were planted at each trial site. The first plot was treated two times at a nominal rate of 0.54 lbs ai/acre/application (1.1x the maximum single application rate), once at the 6-leaf stage and once at the 8-leaf stage (total treatment 1.08 lbs ai/acre; 1.1x maximum seasonal application rate). The second plot was treated at a nominal rate of 0.54 lbs ai/acre (1.1x the maximum single application rate) at the 2-leaf stage, and then treated at a nominal rate of 0.35 lbs ai/acre (0.7x the maximum single application rate) at the 6-leaf stage and finally once at a nominal rate of 0.54 lbs ai/acre (1.1x the maximum single application rate) at the 10-leaf stage (total treatment 1.44 lbs ai/acre; 1.5x maximum seasonal application rate). All applications were made over the top with broadcast spray equipment in 10 gallons of water per acre. The sugar beets from each plot were harvested at maturity. After collection, the tops plus the crown tissue were cut from the roots and packaged separately. All samples were frozen within 2 hours of harvest and shipped frozen to the AgroEvo Research Center for homogenization. The homogenized samples were shipped frozen to Xenos laboratories (Ottawa, Ontario) where they were kept frozen until analysis.

Samples were analyzed for residues of glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate using method BK/04/95 (essentially the same as HRAV-5A, LOQ = 0.05 ppm). This method does not distinguish between glufosinate ammonium and N-acetyl glufosinate. Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated sugar beet tops and roots are summarized in Table 13. The petitioner indicated that this study was conducted according to GLP standards as specified in 40 CFR 160 except for a few minor exemptions. Samples were stored for a maximum of 6 months prior to extraction and analysis (adequate storage stability studies cover this interval). The trial conducted in Canyon, ID was canceled (no explanation was given).

Table 13: Residues in/on Transgenic Sugar Beet Tops and Roots

location	total applied (lbs ai/acre)	PHI (days)	tops [1] (ppm)			roots [1] (ppm)		
			039866/ 099730	061517	total	039866/ 099730	061517	total
Ottawa, MI	1.08	109	0.143 0.163	<0.05 0.051	<0.148 0.214	0.122 0.128	0.053 0.059	0.175 0.187
	1.43	109	0.295 0.297	<0.05 <0.05	<0.300 <0.302	0.239 0.212	0.050 <0.05	0.289 <0.262
Fayette, OH	1.08	83	0.159 0.157	<0.05 <0.05	<0.164 <0.162	0.273 0.119	<0.05 <0.05	<0.323 <0.169
	1.43	77	0.459 0.461	<0.05 <0.05	<0.464 <0.466	0.558 0.780	<0.05 <0.05	<0.608 <0.830 **HAFT = 0.719**
Cass, ND	1.08	67	0.251 0.241	<0.05 <0.05	<0.256 <0.246	0.172 0.163	<0.05 <0.05	<0.222 <0.213

location	total applied (lbs ai/acre)	PHI (days)	tops [1] (ppm)			roots [1] (ppm)		
			039866/ 099730	061517	total	039866/ 099730	061517	total
	1.43	62	0.645 0.530	<0.05 <0.05	<0.649 <0.535	0.535 0.695	<0.05 <0.05	<0.585 <0.745
Scotts Bluff, NB	1.08	115	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10
	1.43	108	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10	0.073, 0.054	<0.05 <0.05	<0.123 <0.104
Ward, ND	1.08	73	0.129 0.156	<0.05 <0.05	<0.134 <0.161	0.118 0.137	<0.05 <0.05	<0.168 <0.187
	1.43	66	0.230 0.235	0.057 0.076	0.287 0.311	0.280 0.326	0.072 0.113	0.352 0.439
Weld, CO	1.08	80	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10	<0.05 <0.05	<0.05 <0.05	<0.10 <0.10
	1.43	68	0.376 0.383	<0.05 <0.05	<0.381 <0.388	0.526 0.549	<0.05 <0.05	<0.576 <0.599
Weld, CO	1.08	86	0.061 0.056	<0.05 <0.05	<0.111 <0.106	0.106 0.112	<0.05 <0.05	<0.156 <0.162
	1.43	81	0.221 0.238	<0.05 <0.05	<0.226 <0.243	0.273 0.304	<0.05 <0.05	<0.323 <0.354
Fresno, CA	1.08	132	<0.05 0.065	<0.05 <0.05	<0.10 <0.10	0.059 0.084	0.065 0.058	0.124 0.142
	1.43	122	0.185 0.260	0.057 0.075	0.242 0.335	0.371 0.357	0.055 0.066	0.426 0.423
Jerome, ID	1.08	128	0.106 0.067	<0.05 <0.05	<0.156 <0.117	0.072 0.063	<0.05 <0.05	<0.122 <0.113
	1.43	121	0.315 0.298	0.058 0.052	0.373 0.350	0.189 0.216	<0.05 <0.05	<0.239 <0.266

HAFT = highest average field trial

[1] concentrations expressed in terms of glufosinate free acid equivalents; HOE prefix eliminated; 039866 glufosinate ammonium, 099730 = N-acetyl glufosinate, 061517 = 3-methylphosphinico propionic acid

Summary Sugar Beet: The petitioner has requested a sugar beet top tolerance of 1.3 ppm and a sugar beet root tolerance of 0.7 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

The two submitted sugar beet field trial studies are adequate (MRIDs 443586-02 and -03). The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid

and N-acetyl glufosinate in/on transgenic sugar beet tops and roots treated with Liberty™ Herbicide at 1.1x - 1.5x the maximum proposed seasonal use rate ranged from <0.10 -1.30 ppm (tops) and <0.10 - <0.830 ppm (roots). Pre-harvest intervals ranged from 41 - 139 days. Only 4 of the 14 field trials had a pre-harvest interval less than 80 days (label specifies a PHI = 60 days). The label indicates that the product may be applied from the cotyledon to 10 leaf stage of the sugar beet. The final application for all field trials was either at the 8 or 10 leaf stage and samples were harvested when the crop reached maturity. Since crop harvest was governed by crop development and the increased PHIs were counteracted in some cases by application rates 1.5x the maximum proposed rate, HED concludes that the field trial data is acceptable. Geographical distribution of the submitted field trials is adequate for establishment of a tolerance in/on sugar beets.

HED concludes that based on the submitted field trial data, the appropriate tolerance in/on sugar beet tops and roots, as result of the application of glufosinate ammonium as defined in this petition, is 1.5 ppm and 0.9 ppm, respectively. The petitioner must submit a revised Section F proposing a 1.5 ppm tolerance in/on sugar beet tops and a 0.9 ppm tolerance in/on sugar beet roots for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

POTATO

MRID 44583901: Magnitude of Glufosinate-Ammonium In or On Potatoes Resulting From a Single Application of Rely® Herbicide, USA 1997: A total of 20 field trials were conducted during 1995 in New York (n=1; Region 1), Pennsylvania (n=2; both in Region 1), New Jersey (n=2; both in Region 2), Florida (n=2; both in Region 3), Illinois (n=1; Region 5), Minnesota (n=1; Region 5), Iowa (n=1; Region 5), North Dakota (n=1; Region 5), Utah (n=2; both in Region 9), California (n=1; Region 10) and Idaho (n=6; all in Region 11). One control and one treated plot were planted at each trial site. The treated plot received a single application of glufosinate-ammonium at 0.40 lbs ai/acre (1.1x the maximum proposed seasonal application rate) 5-7 days after plant senescence began. All applications were made over the top with broadcast spray equipment in 10 gallons of water per acre. Samples were harvested by hand 9-10 days after treatment. All samples were transferred to a freezer within 5 hours of harvest and shipped frozen to the AgroEvo Research Center (Pikeville, NC) for homogenization. The homogenized samples were shipped frozen to Xenos laboratories (Ottawa, Ontario) where they were kept frozen until analysis.

Samples were analyzed for residues of glufosinate ammonium and 3-methylphosphinico propionic acid using method BK/05/95 (LOQ = 0.05 ppm). This method is a modification of HRAV-5A (the anion exchange cleanup step is eliminated). Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated potatoes are summarized in Table 14. The petitioner indicated that this study **was** conducted according to GLP standards as specified in 40 CFR 160 except for a few minor exceptions. Samples were stored for a maximum of 7 months prior to extraction and analysis (adequate transgenic sugar beet storage stability study covers this interval).

Table 14: Residues in/on Potatoes

location	ppm [1]		
	HOE 039866	HOE 061517	total
Wayne, NY	<0.05, <0.05	<0.05, <0.05	<0.10, <0.10
Lehigh, PA	0.288, 0.277	<0.05, <0.05	<0.338, <0.327

location	ppm [1]		
	HOE 039866	HOE 061517	total
Berks, PA	0.098, 0.125	<0.05, <0.05	<0.148, <0.175
Salem, NJ	0.072, 0.117	<0.05, <0.05	<0.122, <0.167
Middlesex, NJ	0.136, 0.146	<0.05, <0.05	<0.186, <0.196
Collier, FL	0.369, 0.276	<0.05, <0.05	<0.419, <0.326
Lee, FL	0.607, 0.617	<0.05, <0.05	<0.657, <0.667 **HAFT = 0.662**
Clinton, IL	0.055, <0.05	<0.05, <0.05	<0.105, <0.10
Freeborn, MN	0.434, 0.329	<0.05, <0.05	<0.484, <0.379
Gerro Gordo, IA	0.190, 0.162	<0.05, <0.05	<0.240, <0.212
Grand Forks, ND	<0.05, <0.05	<0.05, <0.05	<0.10, <0.10
Cache, UT	0.246, 0.240	<0.05, <0.05	<0.296, <0.290
Box Elder, UT	<0.05, <0.05	<0.05, <0.05	<0.10, <0.10
Tulare, CA	<0.05, <0.05	<0.05, <0.05	<0.10, <0.10
Franklin, ID	0.130, 0.120	<0.05, <0.05	<0.180, <0.170
Power, ID	0.247, 0.262	<0.05, <0.05	<0.297, <0.312
Bingham, ID	0.132, 0.094	<0.05, <0.05	<0.182, <0.144
Cassia, ID	0.117, 0.132	<0.05, <0.05	<0.167, <0.182
Bannock, ID	<0.05, 0.073	<0.05, <0.05	<0.10, <0.10
Bonneville, ID	0.160, 0.159	<0.05, <0.05	<0.210, <0.209

HAFT = highest average field trial

[1] concentrations expressed in terms of glufosinate free acid equivalents; HOE 039866 = glufosinate ammonium, HOE 061517 = 3-methylphosphinico propionic acid

Summary, Potatoes: The petitioner has requested a potato tolerance of 0.4 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

The submitted potato field trial study is adequate (MRID 44583901). The combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in/on potatoes treated with Rely® Herbicide at 1.1x the maximum proposed seasonal use rate (PHI = 9-10 days) ranged from <0.10 - <0.667 ppm. Geographical distribution of the submitted field trials is adequate for establishment of a tolerance in/on potatoes.

HED concludes that based on the submitted field trial data, the appropriate tolerance in/on potatoes, as result of the application of glufosinate ammonium as defined in this petition, is 0.8 ppm. The petitioner

must submit a revised Section F proposing a 0.8 ppm tolerance in/on potatoes for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

OPPTS GLN 860.1520: Processed Food/Feed

CANOLA

MRID 44358610: Determination of HOE 039866 Residues and its Metabolites HOE 085355 and HOE 061517 in Processed Fractions of Transgenic Canola Seed Treated with Glufosinate-Ammonium: A single field trial was conducted at Indian Head, Saskatchewan. Four plots were established, an untreated control and three plots treated at the 4-6 leaf stage with a single application of glufosinate ammonium at 0.67 lbs ai/acre (0.9x the maximum seasonal rate), 1.3 lbs ai/acre (1.8x the maximum seasonal rate) or 3.3 lbs ai/acre (4.5x the maximum seasonal rate). All applications were made with broadcast spray equipment in ~12 gallons of water per acre. Grain samples were collected 70 days after application. After mechanical thrashing and cleaning, all grain samples were transferred to a freezer. Approximately 5 kg of seed from each treatment were shipped to the Food Protein Research and Development Center, Texas A&M University (College Station, Texas) for processing.

Upon receipt to the processing facility the canola samples were dried and cleaned. Following conditioning, the majority of the crude oil was obtained by pressing in an expeller. The residual crude oil remaining in the presscake was extracted with hexane. A portion of the solvent-extracted meal was desolventized and toasted. The crude oil from the press and the extraction were combined and refined. The refined oil was bleached and deodorized. All samples were kept frozen and shipped frozen to Xenos Laboratories (Ottawa, Ontario) for analysis.

Samples were analyzed for residues of glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid using method HRAV-24 (similar to method AE-24, LOQ = 0.05 ppm). Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated canola seed and processed commodities are summarized in Table 15. The petitioner indicated that this study was conducted according to GLP standards as specified in 40 CFR 160 except for a few minor exceptions.

Unprocessed canola seed was stored for a maximum of 7 months prior to extraction and analysis (adequate transgenic soybean storage stability study covers this interval). Canola seed samples were stored 4.5 months prior to processing into canola meal, oil and soapstock. The processed samples were stored for 4 months prior to analysis. Storage stability studies performed on transgenic soybean processed commodities demonstrated that all residue components were stable for 3 months. The storage intervals for the canola processed commodities are acceptable.

Table 15: Concentration/Reduction Factors for Canola Processed Commodities

commodity	ppm [1]				reduction/concentration factors [2]			
	HOE 039866	HOE 061517	HOE 099730	total	HOE 039866	HOE 061517	HOE 099730	total
0.67 lbs ai/acre								
seed	<0.05	<0.05	0.063	<0.163	--	--	--	--
untoasted	<0.05	<0.05	0.170	<0.270	--	--	2.7	1.9
toasted meal	<0.05	<0.05	0.206	<0.306	--	--	3.3	2.3
oil [3]	<0.05	<0.05	<0.05	<0.15	--	--	0.4	0.7
soapstock	<0.05	<0.05	<0.05	<0.15	--	--	0.4	0.7
1.3 lbs ai/acre								
seed	<0.05	<0.05	0.060	<0.160	--	--	--	--
untoasted	<0.05	<0.05	0.222	<0.322	--	--	3.7	2.5
toasted meal	<0.05	0.054	0.292	<0.396	--	2.2	4.9	3.4
oil [3]	<0.05	<0.05	<0.05	<0.15	--	--	0.4	0.7
soapstock	<0.05	<0.05	<0.05	<0.15	--	--	0.4	0.7
3.3 lbs ai/acre								
seed	<0.05	<0.05	0.211	<0.311	--	--	--	--
untoasted	<0.05	0.108 [4]	0.604 [4]	<0.762	--	4.3	2.9	2.8
toasted meal	<0.05	0.105	0.638	<0.793	--	4.2	3.0	2.9
oil [3]	<0.05	<0.05	<0.05	<0.15	--	--	0.1	0.3
soapstock	<0.05	<0.05	0.083	<0.183	--	--	0.4	0.5

[1] concentrations expressed in terms of glufosinate free acid equivalents; HOE 039866 = glufosinate ammonium, HOE 099730 = N-acetyl glufosinate, HOE 061517 = 3-methylphosphinico propionic acid

[2] residues <0.05 ppm were placed at ½ LOQ (0.025 ppm) for determination of reduction/concentration factors

[3] residues in crude oil, refined oil, refined bleached oil and refined bleached deodorized oil were <0.05 ppm

[4] average of replicate analysis

Summary Canola Processing Studies: The petitioner has requested a canola meal tolerance of 2.0 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

The submitted canola processing study is adequate (MRID 44358610). Canola seed harvested 70 days after treatment with glufosinate ammonium at 0.67, 1.3 or 3.3 lbs ai/acre/application (0.9x, 1.7x and 4.3x the maximum seasonal application rates; treated at 4-6 leaf stage) was processed into meal, oil and soapstock. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate did not concentrate in oil or soapstock but did concentrate 3.4x and 2.9x in toasted meal (average 3.2x). Since both metabolites were detected in toasted meal from the two highest treatment groups, only concentration factors from these groups were considered.

The highest field trial for canola seed was <0.336 ppm (Indian Head, Sk; MRID 44358609). The maximum combined glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate residue expected in/on transgenic canola meal, based on the highest field trial and the 3.2x concentration factor, is 1.1 ppm.

HED concludes that the appropriate tolerance in/on canola meal, as a result of the application of glufosinate ammonium to canola as defined in this petition, is 1.1 ppm. The petitioner must submit a revised Section F proposing a canola meal tolerance of 1.1 ppm for the combined residues of glufosinate ammonium and its metabolites N-acetyl glufosinate ammonium and 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

SUGAR BEET

MRID 44358604: Magnitude of Glufosinate-Ammonium Residues In or On Transgenic Sugar Beet Roots and Processed Commodities Resulting from Multiple Applications of Liberty™ Herbicide, USA, 1996: A single field trial was conducted at Fresno, California. Two plots were established, a untreated control and a treated plot which received three applications (2-leaf stage, 6-leaf stage and 8-leaf stage) of glufosinate ammonium at 2.5 - 2.7 lbs ai/acre/application (total applied 7.9 lbs ai/acre; 8.3x the maximum proposed seasonal application rate). All applications were made with broadcast spray equipment in ~10 gallons of water per acre. The sugar beet plants were allowed to grow to maturity and harvested by hand 136 days after the final application. Samples were transferred to a freezer within 10 minutes of collection. Samples were shipped frozen to Wm. J. Engler Associates, Inc. (Moses Lake, Washington) for processing into dried pulp, molasses and refined sugar.

The sugar beets were removed from frozen storage and a representative RAC was collected as an unprocessed sample. The sugar beets were washed and cut into slabs. Sugar was extracted in a series of steam heated cells with a mixture of fresh water and pulp press water. Extracted beet pulp was pressed to recover the sugar solution carried out with the pulp. The pressed pulp was dried to 1.7% moisture, milled and collected. The raw juice was purified in a stem jacketed kettle by addition of lime and carbon dioxide. The precipitate was allowed to settle and clarified juice was decanted and screened. The settled sludge was vacuum filtered and the filtrate combined with the decanted liquid. The clarified juice was further purified by a second carbonation with carbon dioxide gas and then vacuum filtered, concentrated and placed in frozen storage for later processing. The juice was thawed and filtered. The filtered thick juice was fed to a Laboratory Vacuum Pan and Granulator. The massecuite (mixture of sugar crystals and syrup) was centrifuged in a perforated bronze basket. The spun off syrup (molasses) was collected. Sugar retained in the basket was washed, dried and collected. Samples of the whole beet and processed commodities were shipped frozen to the ARC where the whole beets were homogenized. All samples were shipped frozen to Xenos Laboratories (Ottawa, Ontario) where they remained frozen until analysis.

Samples were analyzed for residues of glufosinate ammonium, N-acetyl glufosinate and 3-methylphosphinico propionic acid using method BK/04/95 (method is similar to HRAV-5A, LOQ = 0.05 ppm all sugar beet matrices). This method does not distinguish between glufosinate ammonium and N-acetyl glufosinate. Apparent residues were less than the LOQ in/on all untreated samples. Residues in/on treated sugar beet and processed commodities are summarized in Table 16. The petitioner indicated that this study **was** conducted according to GLP standards as specified in 40 CFR except for a few minor exceptions.

Unprocessed sugar beet samples were stored for a maximum of 5 months prior to extraction and analysis (an adequate sugar beet storage stability study cover this interval). Sugar beet samples were stored 2 months prior to processing into pulp, molasses and sugar. The processed samples were stored for 3 months prior to analysis. No storage stability data for sugar beet pulp, molasses or sugar have been submitted.

Table 16: Concentration/Reduction Factors for Sugar Beet Processed Commodities

commodity	ppm [1]			reduction/concentration factors [2]		
	HOE 039866/099730	HOE 061517	total	HOE 039866/099730	HOE 061517	total
Roots	0.228	0.929	1.157	--	--	--
Dried Pulp	0.141	0.585	0.726	0.6	0.6	0.6
Molasses	1.58	6.33	7.91	6.9	6.8	6.8
Refined Sugar	<0.05	<0.05	<0.10	0.1	<0.1	<0.1

[1] concentrations expressed in terms of glufosinate free acid equivalents; HOE 039866 = glufosinate ammonium, HOE 099730 = N-acetyl glufosinate, HOE 061517 = 3-methylphosphinico propionic acid

[2] residues <0.05 ppm were placed at ½ LOQ (0.025 ppm) for determination of reduction/concentration factors

Summary Sugar Beet Processing Study: The petitioner has requested a sugar beet molasses tolerance of 5.0 ppm for the combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate expressed as glufosinate free acid equivalents.

Sugar beets treated three times with Liberty™ Herbicide (2-leaf stage, 6-leaf stage and 8-leaf stage) at 2.5 - 2.7 lbs ai/acre/application (total applied 7.9 lbs ai/acre; 8.3x the maximum proposed seasonal application rate) were harvested 136 days after the final treatment and processed into pulp, molasses and sugar. The combined residues of glufosinate ammonium and its metabolites 3-methylphosphinico propionic acid and N-acetyl glufosinate did not concentrate in pulp or sugar but did concentrate 6.8x in molasses. Unprocessed sugar beet samples were stored for 5 months prior to analysis (adequate storage stability study covers this interval). Processed samples were stored for 3 months prior to analysis. No storage stability data for sugar beet pulp, molasses or sugar have been submitted.

The highest average field trial (HAFT) for sugar beet roots was 0.719 ppm (Fayette, OH; MRID 44358603). The maximum combined glufosinate ammonium, 3-methylphosphinico propionic acid and N-acetyl glufosinate residue expected in sugar beet molasses, based on the HAFT and the 6.8x concentration factor, is 5.0 ppm.

HED will not be opposed to conditional registration of glufosinate ammonium on transgenic sugar beets. Unconditional registration may be granted upon validation of the three month storage interval for the processed commodities (sugar, pulp and molasses). Pending submission and evaluation of this data, HED concludes that the petitioners proposed sugar beet molasses tolerance of 5.0 ppm, is appropriate.

POTATO

MRID 44358612: Glufosinate-Ammonium Derived Residues in Potatoes and Processed Commodities Following Vine Desiccation with Ignite at the Minimum Recommended PHI - USA, 1996: A single field trial was conducted at Ephrata, Washington. Two plots were established, an untreated control and a treated plot which received a single application of glufosinate ammonium at 2.0 lbs ai/acre (5.3x the maximum single and seasonal application rate). All applications were made with broadcast spray equipment in ~12 gallons of water per acre. Potatoes were harvested 9 days after application using a single row mechanical digger. The samples were shipped frozen to Xenos Laboratories (Ottawa, Ontario) and fresh to Wm. J. Engler and Associates, Inc. (Moses Lake, Washington) for processing into chips, flakes and wet peel.

Potato Chip Processing: Potatoes were washed, peeled and cut into ~0.16cm slices. The sliced potatoes were placed in warm water to remove free starch. The slices were drained over a screen to remove excess water and were fried in oil at ~180° C for 90 seconds. The fried potatoes were drained and salted. A sample of the potato chips was collected and placed in the freezer.

*Potato Flake **Processing:*** Potatoes were washed and batch steamed for 45 seconds (6.0 kg/cm^2). The steamed potatoes were scrubbed for 30 seconds and the potato peel collected. The collected peel was hydraulically pressed and combined with the cut trim waste and placed in the freezer. The peeled potatoes were cut into ~1.3 cm slabs and sprayed washed to remove free starch. The potato slabs were precooked at ~74° C for 20 minutes and cooled. The cooled potato slabs were steam cooked at ~100° C for 40 minutes, mashed and mixed with an emulsion of food additives. The wet mash was placed in a Overton Single Drum Dryer to dry the wet mash into a thin sheet. The dried potato mash was broken into large flakes by hand and placed on a fluidized bed dryer 3-5 minutes to complete the drying process. The flakes were feed into a hammermil for uniform milling of the finished potato flakes. A sample of the flakes was collected and frozen.

Samples of unprocessed potatoes, potato chips, potato flakes and wet peel were shipped frozen to Xenos Laboratories for analysis. Samples were analyzed for residues of glufosinate ammonium and its metabolite, 3-methylphosphinico propionic acid, using method XAM-24B (LOQ = 0.05 ppm, method is similar to HRAV-5A). Residues in/on treated potatoes and processed commodities are summarized in Table 17. The petitioner indicated that this study **was** conducted according to GLP standards as specified in 40 CFR except for a few minor exemptions.

Potato samples were processed within two days of collection. Processed and unprocessed potato samples were stored for a maximum of 3 months prior to extraction and analysis. Since processed potato commodities are not substantially different from the unprocessed commodity, the validated storage interval for transgenic sugar beet root samples of 24 months will be considered applicable to both processed and unprocessed potato commodities. The storage intervals for this study are within predetermined limits.

Table 17: Concentration/Reduction Factors for Potato Processed Commodities

commodity	ppm [1]			reduction/concentration factors [2]		
	HOE 039866	HOE 061517	total	HOE 039866	HOE 061517	total
potato	0.641	<0.05	<0.691	--	--	--
potato chips	1.49	<0.05	<1.54	2.3	--	2.3
potato flakes	1.96	<0.05	<2.01	3.1	--	3.0
potato wet peel	0.358	<0.05	<0.408	0.6	--	0.6

[1] concentrations expressed in terms of glufosinate free acid equivalents; HOE 039866 = glufosinate ammonium, HOE 061517 = 3-methylphosphinico propionic acid

[2] residues <0.05 ppm were placed at ½ LOQ (0.025 ppm) for determination of reduction/concentration factors

Summary Potato Processing Study: The petitioner has requested a potato flake tolerance of 1.3 ppm and a processed potato tolerance of 1.0 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

The submitted potato processing study is adequate (MRID 44358612). Potatoes harvested 9 days after a single treatment with glufosinate ammonium at 2.0 lbs ai/acre (5.3x the maximum proposed single and seasonal application rate) were processed into chips, flakes and peel. Glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid did not concentrate in potato peel but did concentrate 2.3x in potato chips and 3.0x in potato flakes.

The HAFT for potatoes was 0.662 ppm (Lee, FL; MRID 44583901). The maximum combined glufosinate ammonium and 3-methylphosphinico propionic acid residue expected in potato flakes, based on the HAFT and the 3.0x concentration factor, is 2.0 ppm. The maximum combined glufosinate ammonium and 3-methylphosphinico propionic acid residue expected in potato chips, based on the HAFT and the 2.3x concentration factor, is 1.6 ppm.

HED concludes that the appropriate tolerance in/on potato chips and potato granuales/flakes, as a result of the application of glufosinate ammonium to potatoes as defined in this petition, is 1.6 ppm and 2.0 ppm, respectively. The petitioner must submit a revised Section F proposing a potato chip tolerance of 1.6 ppm and a potato granule/flake tolerance of 2.0 ppm for the combined residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid expressed as glufosinate free acid equivalents.

OPPTS GLN 860.1850 & 860.1900: Confined/Field Accumulation in Rotational Crops

A confined accumulation in rotational crops study has been submitted, reviewed and determined to be adequate (MRID 43766917). Lettuce, radish and spring wheat were planted 28 and 119 days after the soil was treated with glufosinate ammonium at 0.9 lbs ai/acre (MRID 43766917). Based on the levels of extractable residues observed at the 119 day plantback interval, no additional data on rotational crops are required provided a 120 day plant back interval for all crops is placed on the label (D211531 and D219069, M. Rodriquez, 7-Mar-1996). A field rotational crop study performed with winter wheat has been submitted and reviewed (MRID 44432601). Winter wheat was planted 73 - 90 days after the soil was treated with glufosinate ammonium at 0.8 lbs ai/acre. Reported residues on/on treated samples of wheat forage, hay, straw and grain were less than the LOQ (LOQ = 0.05 ppm) (P. Errico [RD], 6-May-1998).

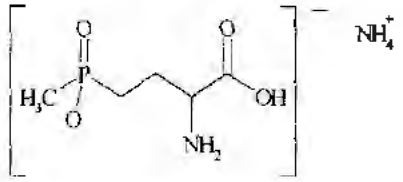
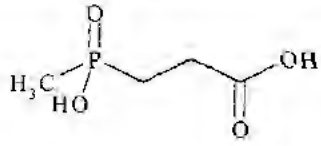
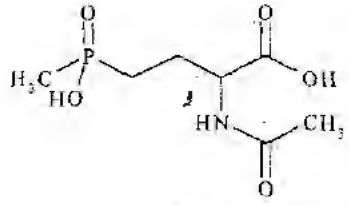
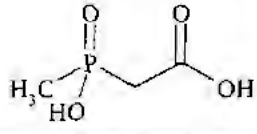
Conclusions: The submitted label indicates a 120 day plant back interval for wheat only. The label should be amended to indicate a 120 day plant back interval for all crops except wheat where a 70 day plant back interval is appropriate.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

-no data submitted

cc: PP 7F04910 & 8F04997, T. Bloem (RAB1)
RDI: M. Morrow (9-Jul-1999), G. Kramer (8-Jul-1999), RAB1 Chemists (20-May-1999)
T. Bloem:806R:CM#2:(703)-605-0217

Attachment 1: Structure of glufosinate-ammonium and its metabolites in potato, transgenic canola and transgenic sugar beet commodities.

Common Name Chemical Name	Structure
glufosinate-ammonium ammonium-DL-homoalanin-4-yl(methyl) phosphinate (HOE 039866)	
3-methylphosphinico propionic acid (HOE 061517)	
N-acetyl-glufosinate 2-acetamido-4-methylphosphinico-butanoic acid (HOE 099730 or HOE 085355) (found only in transgenic crops)	
2-methylphosphinico-acetic acid	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

PC
128850

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

1-April-1998

MEMORANDUM

SUBJECT: PP# 7F04910. Method Validation Request for Glufosinate Ammonia on Sugar Beets and Canola. Chemical 128850. Case 289177. Barcode D254830. Submission S529287.

FROM: Tom Bloem, Chemist
Registration Action Branch I
Health Effects Division (7509C)

THROUGH: Melba Morrow, Senior Scientist
Registration Action Branch I

TO: Francis D. Griffith Jr., Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (7503C)

Method validation is requested for BASF Methods BK/04/95 (sugar beets) and XAM-24 (canola) for the determination of glufosinate ammonia and its metabolites 2-acetamido-4-methylphosphinico-butanoic acid (N-acetyl-glufosinate) and 3-methylphosphinico-propionic acid (3-MP acid). The following supporting data provided by BASF Corporation will be submitted along with this request:

- Determination of HOE 039866 Residue and its Metabolites Hoe 085355 and HOE 061517 in Glufosinate Tolerant Canola (*Brassica Napus*) Generated from 1994 Field Trials -- MRID 443596-09: description of method XAM-24 pages 74-100
- Magnitude of Glufosinate-Ammonia Residues In or On Transgenic Sugar Beets Resulting From Multiple Applications of Liberty™ Herbicide at Three Rates, USA, 1995 -- MRID 443586-02; description of method BK/04/95 pages 78-120

Method BK/04/95 is a variation of the Glufosinate Ammonia Enforcement Method HRAV-5A, with modifications for applications to sugar beets. For both BK/04/95 and HRAV-5A, glufosinate ammonia and N-acetyl-glufosinate are derivatized and quantified as one (3-MP acid is quantified separately).

Method XAM-24 (canola) is a variation of the Glufosinate Ammonia Enforcement Method HRAV-5A, with an additional post-extraction cation exchange procedure to allow for separate detection and measurement of all three regulated compounds (glufosinate ammonia, N-acetyl-glufosinate and 3-MP acid: 40 CFR 180.473c).

Samples should be run in duplicate per the experimental design given in Attachment 1. Please complete and return the requested information on the attached forms and other relevant information concerning the method validation, including copies of chromatograms for representative controls, reference standards, and fortified samples; standard curves, sample calculations, and recommendations to Karen Whitby, Branch Chief, Registration Action Branch I (7509C). Any deficiencies in the method as written and the time required to complete a set of samples should also be noted and reported. If applicable, please confirm if there are convenient overnight stopping points in the method.

Since one of the purposes of the trial is to determine if all necessary instructions are included in the submitted method, we request that the laboratory scientists have minimal contact with the petitioner during the conduct of this trial.

The Registration Division Product Manager is Joanne Miller (703-305-6224). The PM Team Reviewer is Eugene Wilson. Eugene can be reached at 703-605-6103 for additional information regarding the priority for completion of this method validation trial.

Attachments:

1. Reporting Form for the method
2. MRIDs: 443586-02 & 443586-09

cc with Attachment 1 (only): PP#7F04910, Eugene Wilson (RD 7505C), RAB1 File, T. Bloem (RAB1)

ATTACHMENT 1

For all methods: Do not use control values for recovery corrections.
Do not report control values as 0. If less than the limit of detection, report as such.

Method BK 04-95: "Gas Chromatographic Determination of HOE 039866 (Glufosinate Ammonium) and its Metabolites as Residues in Glufosinate-Resistant Sugar Beets (Tops and Roots), and Sugar Beet Processed Commodities" MRID 443586-02: pages 78-120

Commodity	Chemicals Added	PPM Added	PPM Found	% Recovery
sugar beet root	glufosinate ammonium	0.00 0.05 0.35 0.70		
	N-acetyl-glufosinate	0.00 0.05 0.35 0.70		
	3-MP acid	0.00 0.05 0.35 0.70		

Method XAM-24: "Gas Chromatographic Determination of HOE 039866 (Glufosinate Ammonium) and its Metabolites as Residues in Transgenic Canola and Processed Commodities" MRID 443586-09: pages 74-100

Commodity	Chemicals Added	PPM Added	PPM Found	% Recovery
~~sugar beet root~~ Canola	glufosinate ammonium	0.00 0.05 0.20 0.40		
	N-acetyl-glufosinate	0.00 0.05 0.20 0.40		
	3-MP acid	0.00 0.05 0.20 0.40		

-Modifications to method (major or minor):

-Special precautions to be taken:

-Source of analytical standards:

-If derivated standard used, give source:

-If derivated standard used, give source:

-Instrumentation for quantitation:

-Instrumentation for Confirmation:

-If instrument parameters differ from method given, list parameters used:

-Commercial source for any special chemicals or apparatus:

-Comments:

-Chromatograms:

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13544

R062023

Chemical:	**Glufosinate**
PC Code:	**128850**
HED File Code	**11500 Petition Files Chemistry**
Memo Date:	***06/11/2003 12:00:00 AM***
File ID:	**DPD257590; DPD258417; DPD257629; DPD257628; DPD211531; DPD219069; *DPD258420; DPD258416; DPD258075; DPD258415; DPD254830***
Accession Number:	**412-04-0137**

HED Records Reference Center
06/28/2004